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(54) **SURGICAL INSTRUMENTATION AND METHOD FOR TREATMENT OF A SPINAL STRUCTURE**

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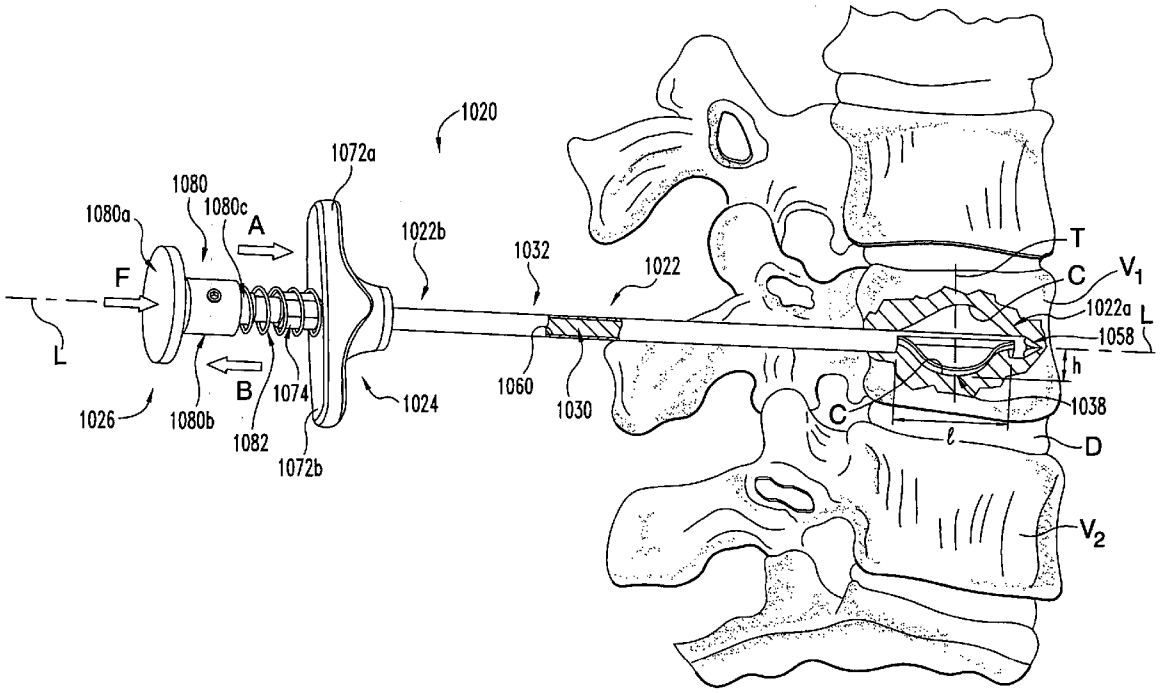
A61F 2/34 (2006.01)

(52) **U.S. Cl.** **606/92**

(57) **ABSTRACT**

Embodiments of the invention include instrumentation and methods for treatment of a spinal structure or other orthopedic structures. An elongate member including a deformable distal portion having an initial configuration for placement within a spinal structure or other orthopedic structures, and a deformed configuration wherein the distal portion is outwardly deformed is provided. The elongated member may be used to access the interior of the spinal structure or other orthopedic structures and to manipulate tissue within the structure.



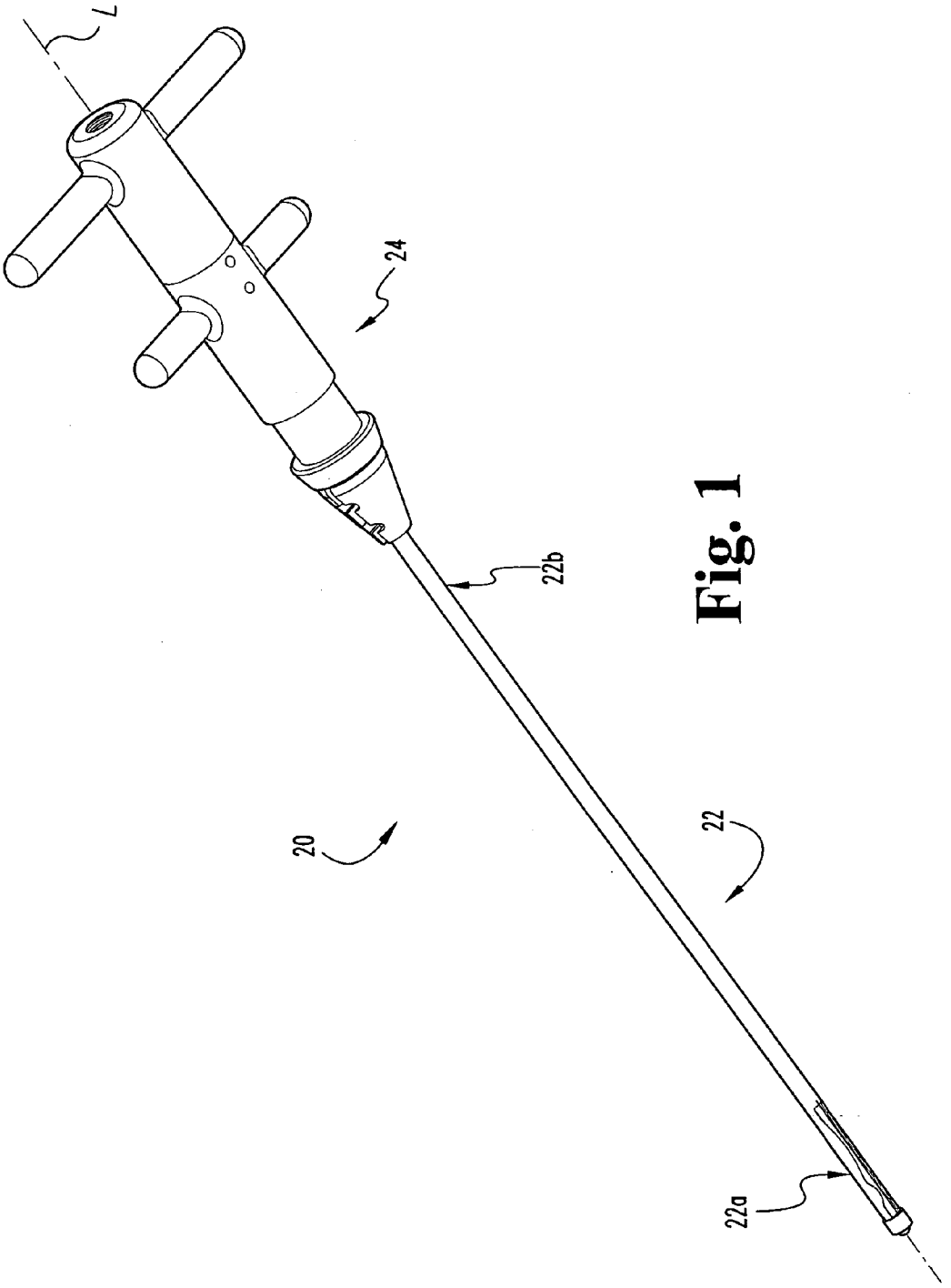
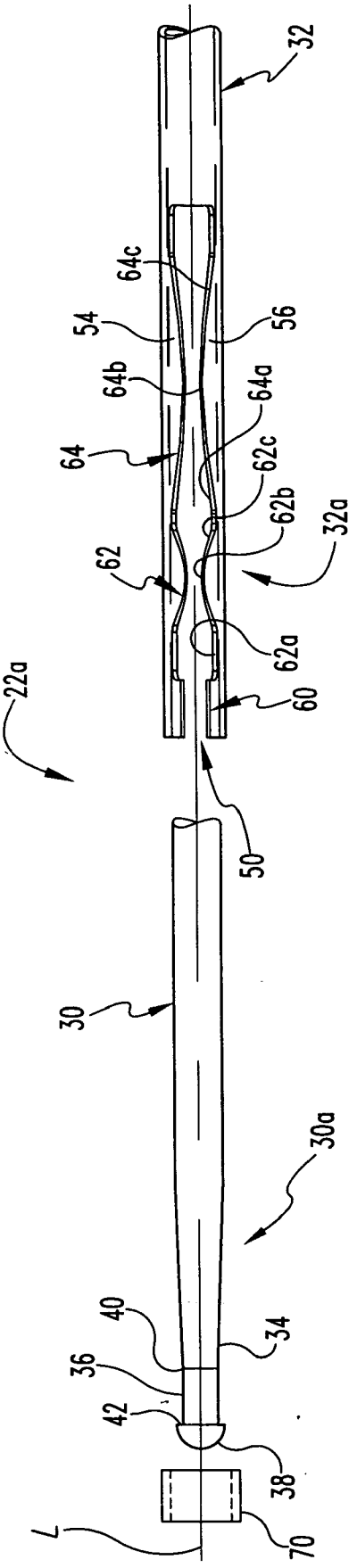


Fig. 1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30a
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70
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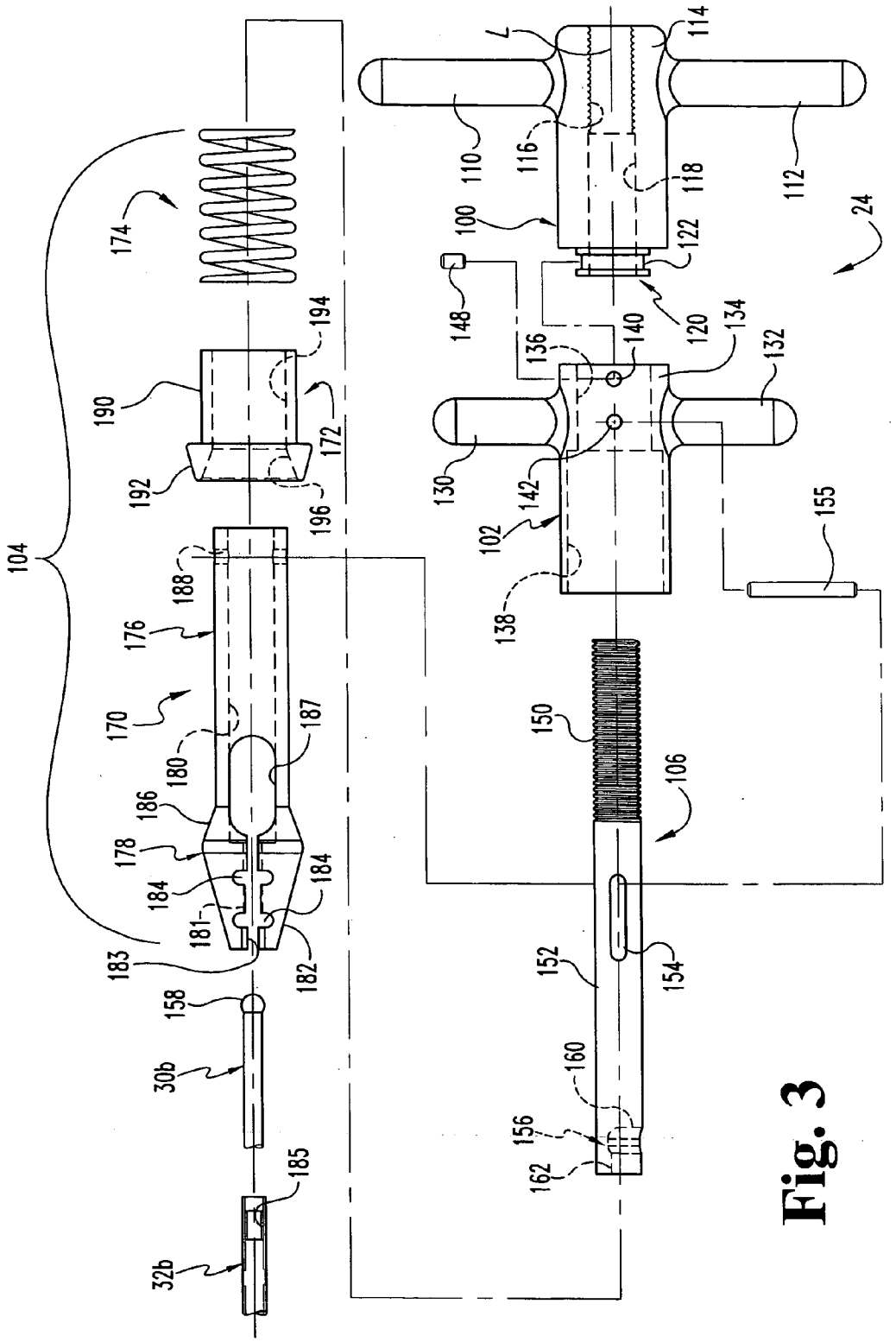
Fig. 2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192
196
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176
170
187
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186
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182
158
30b
185
32b
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106
152
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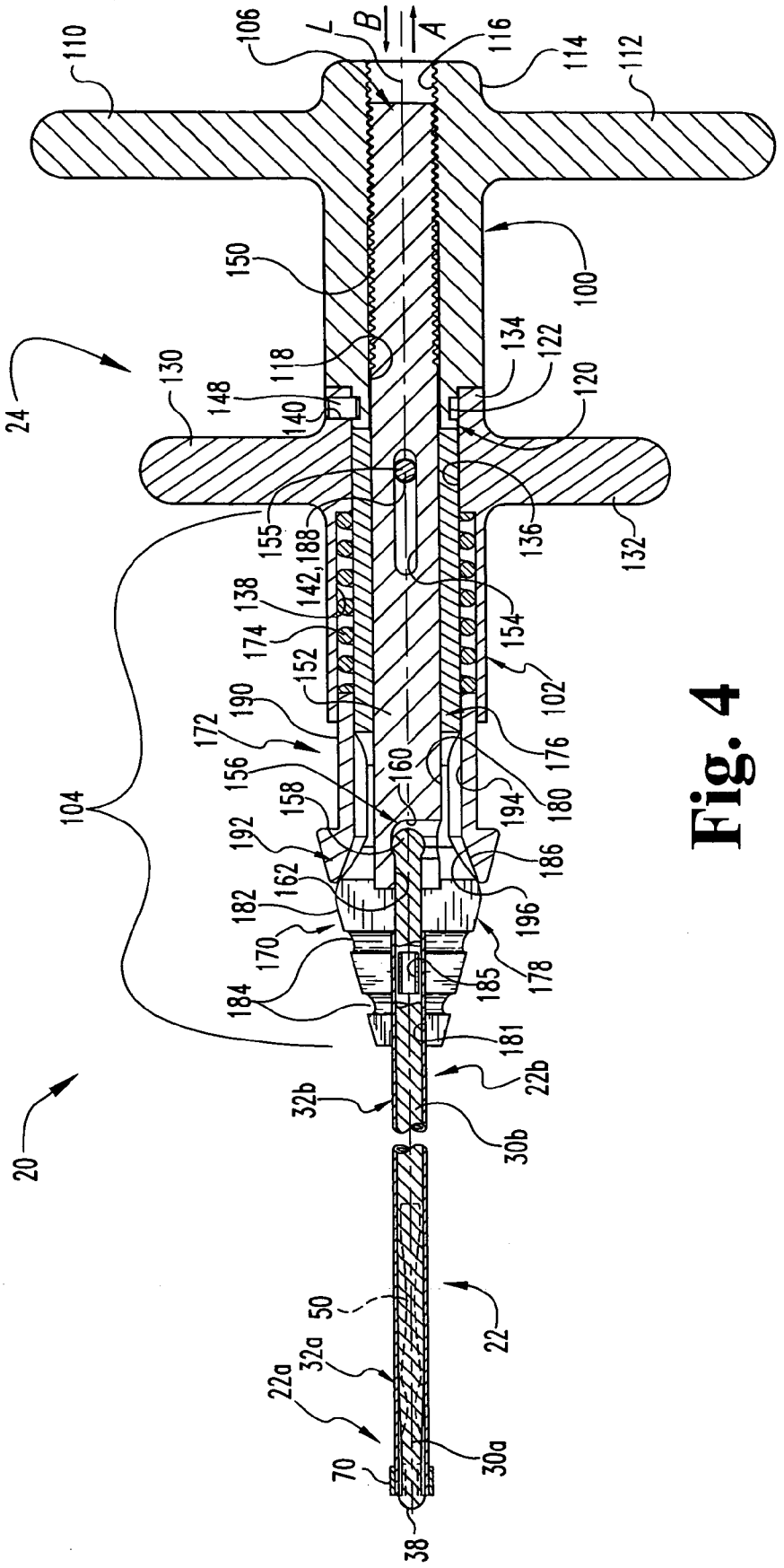
160
156
162

Fig. 3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106
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132
138
174
154
152
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190
172
176
156
160
158
194
180
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192
186
162
182
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50
22
32a
22a
30a
70
38

Fig. 4

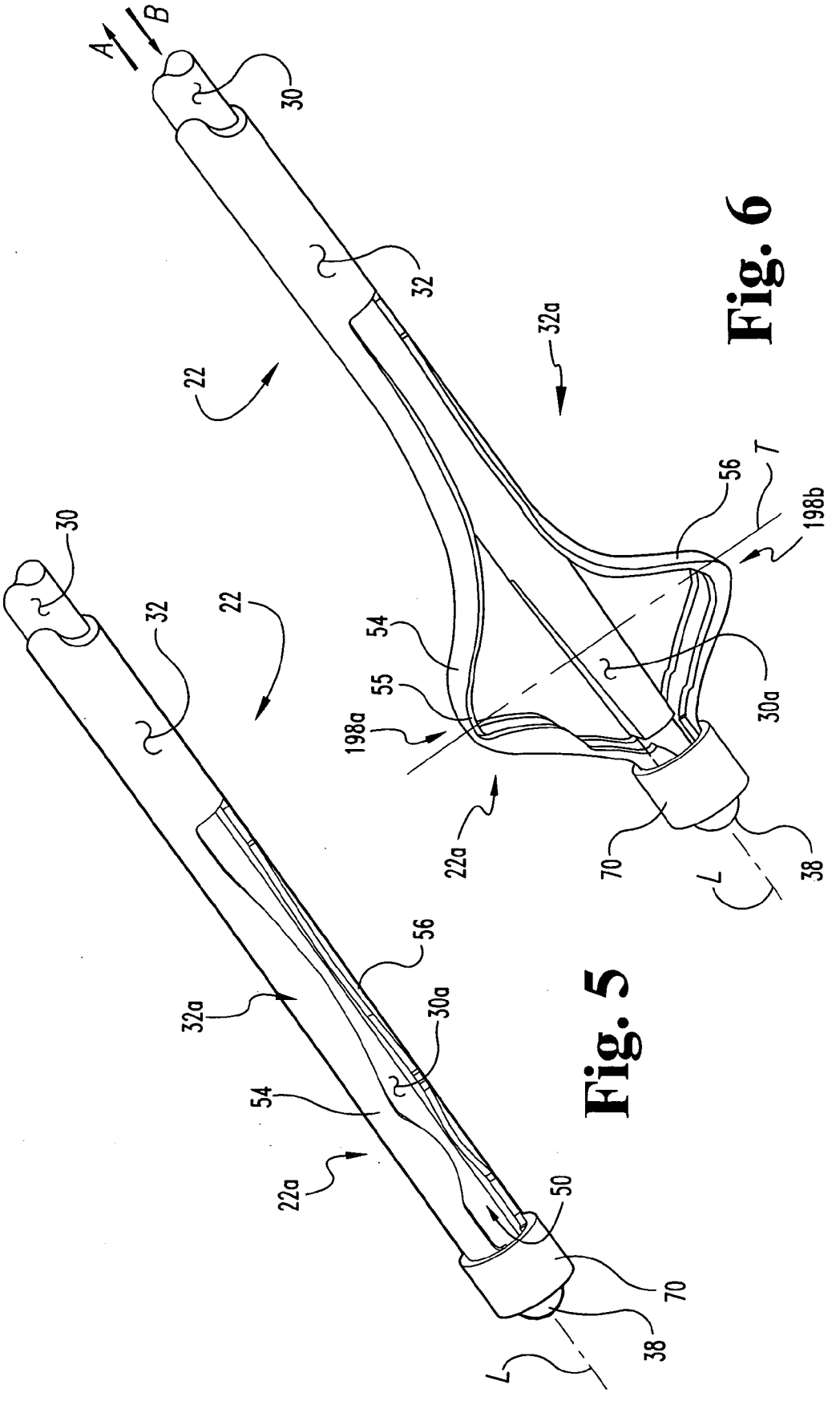
A
B
30
32
22
32a
56
T
198b
54
55
198a
30a
22a
70
38
L

Fig. 6

30
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22
56
32a
30a
54
22a
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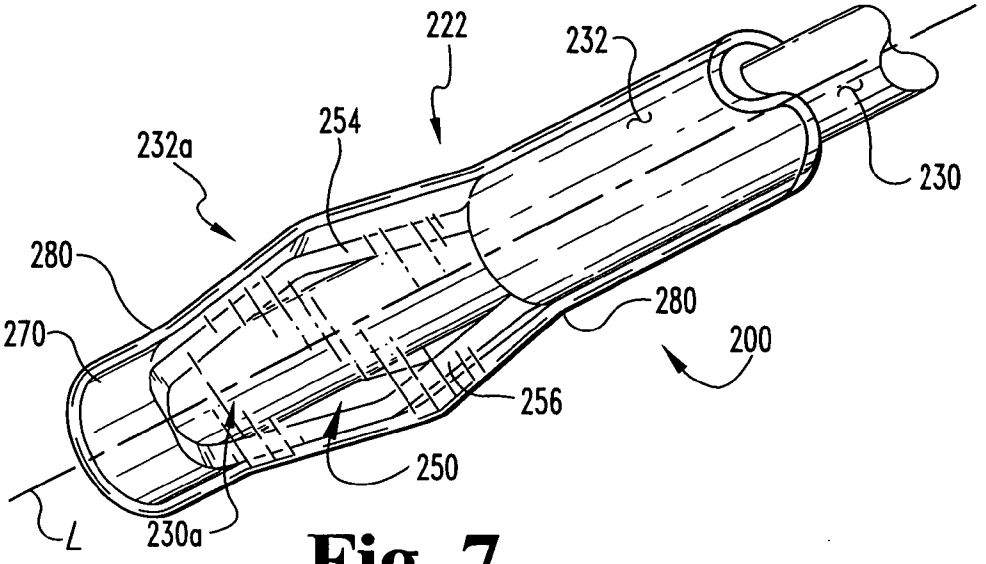
70
38
L

Fig. 5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232a
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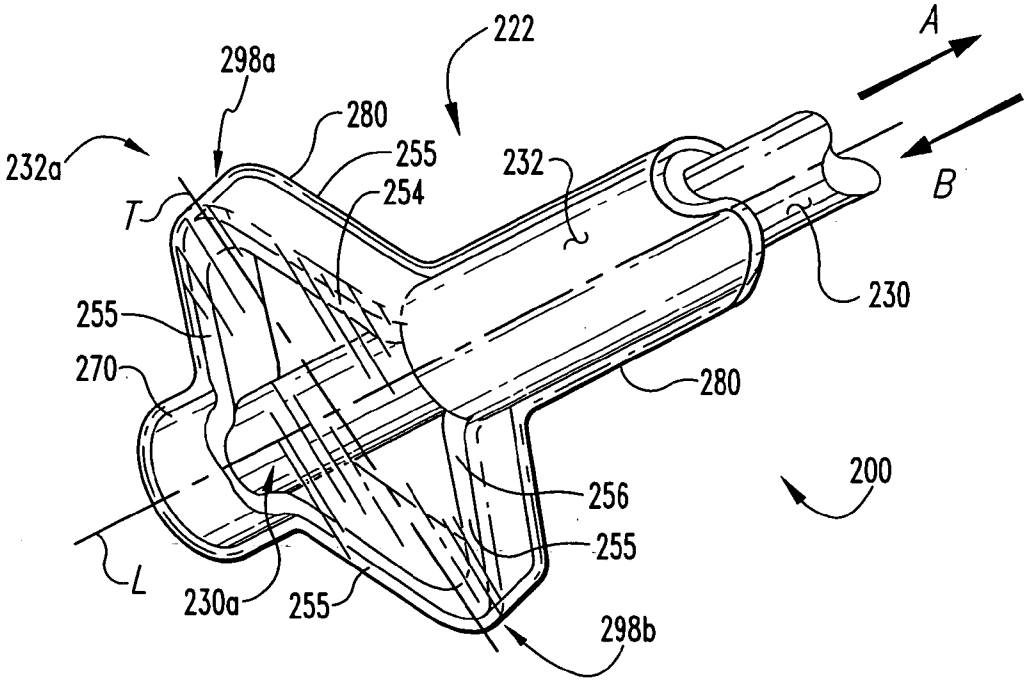
200
256
250
L
230a

Fig. 7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222
298a
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232
254
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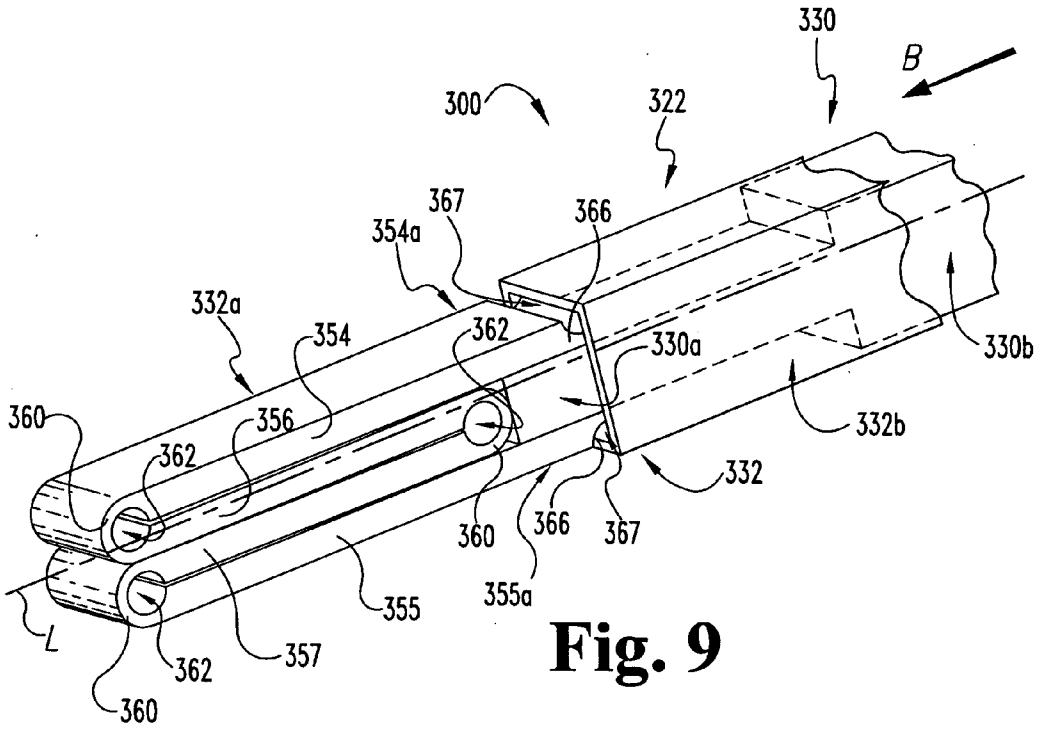
280
200
256
255
L
230a
255
298b

Fig. 8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332a
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332b
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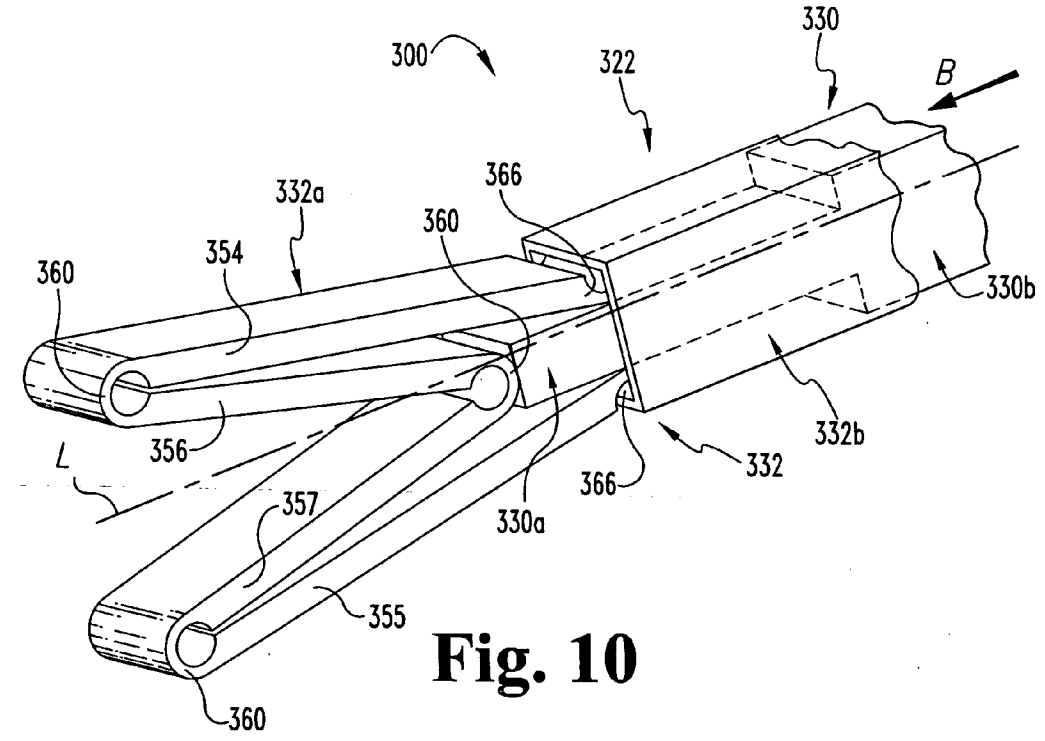
367
355a
355
L
362
357
360

Fig. 9


330
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B
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332a
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330b
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332b
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332
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330a
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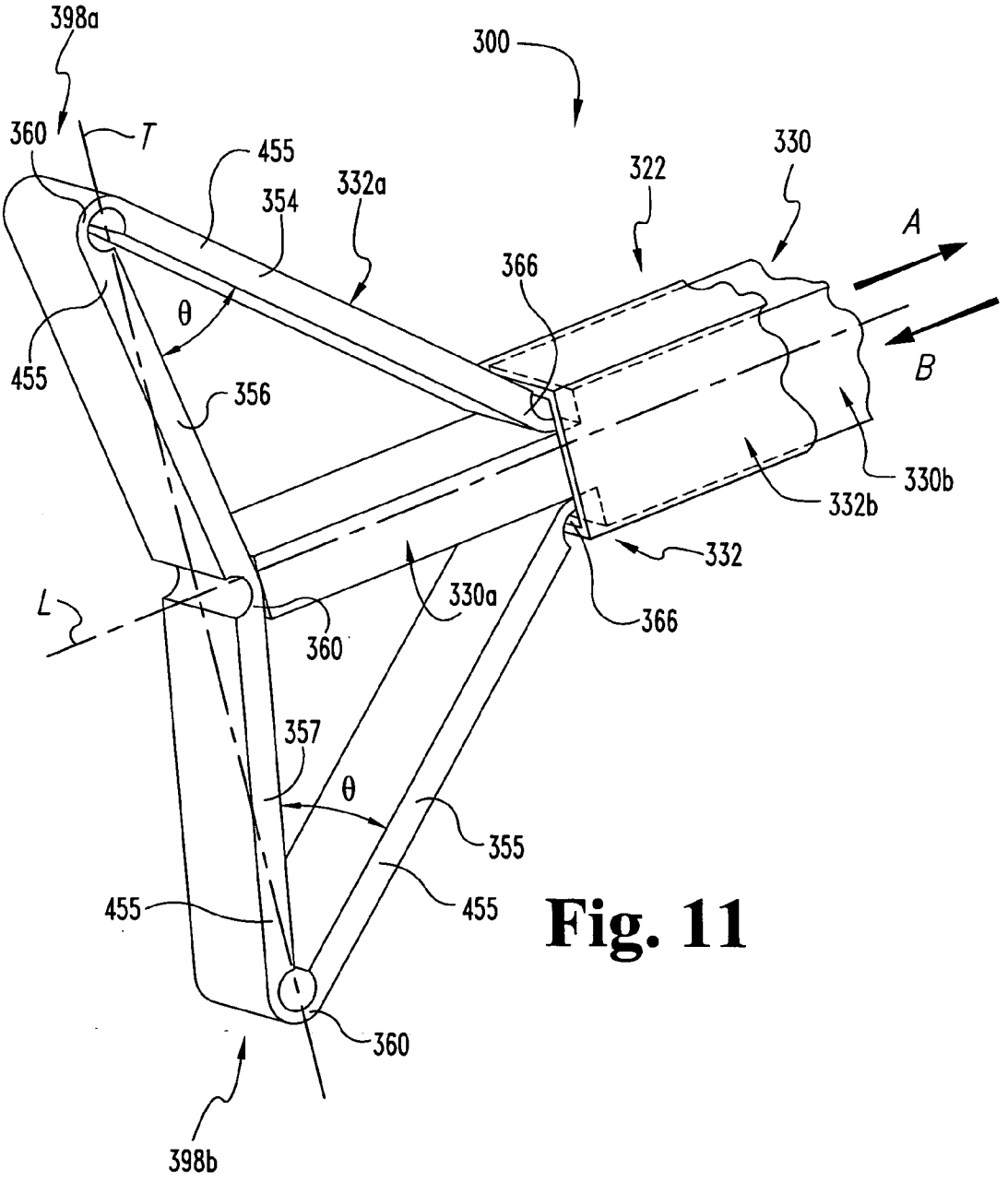
360

Fig. 10


398a
300
360
T
455
354
332a
322
330
A
366
θ
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356
B
330b
332b
332
330a
366
L
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357
θ
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455
455
360
398b

Fig. 11

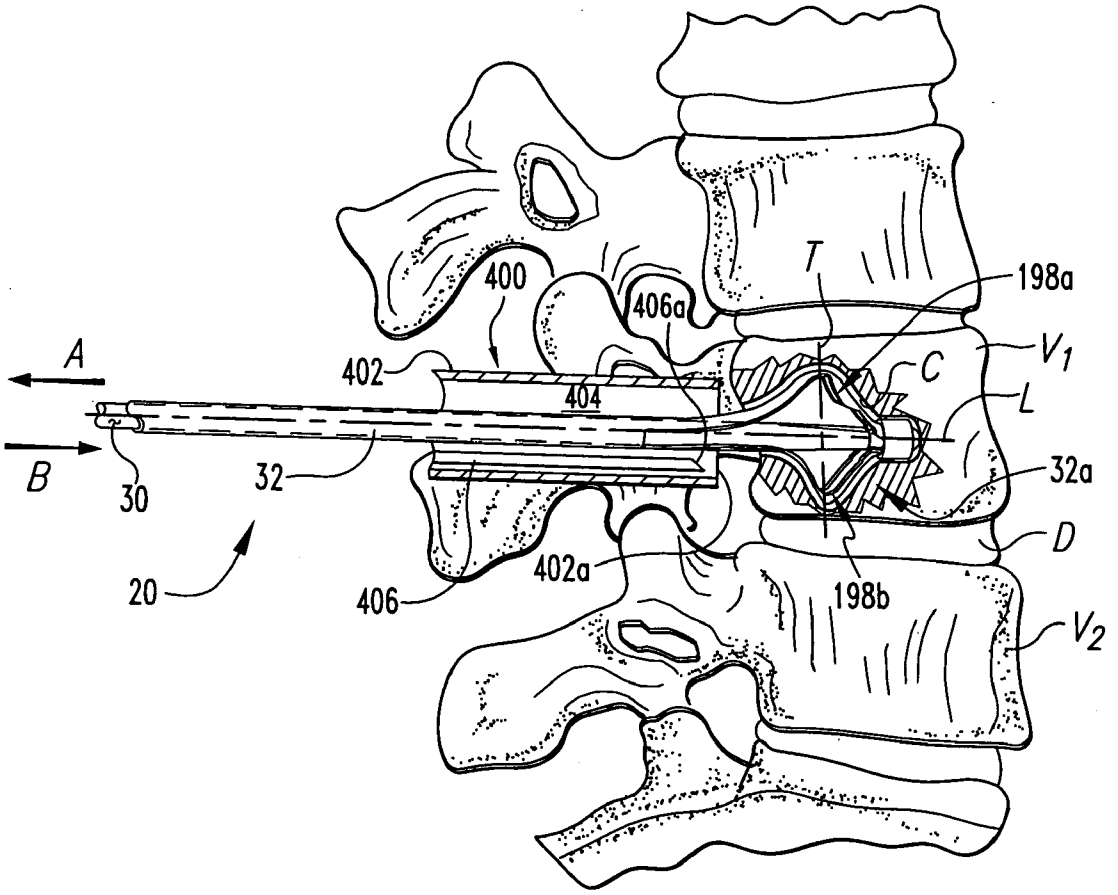


Fig. 12

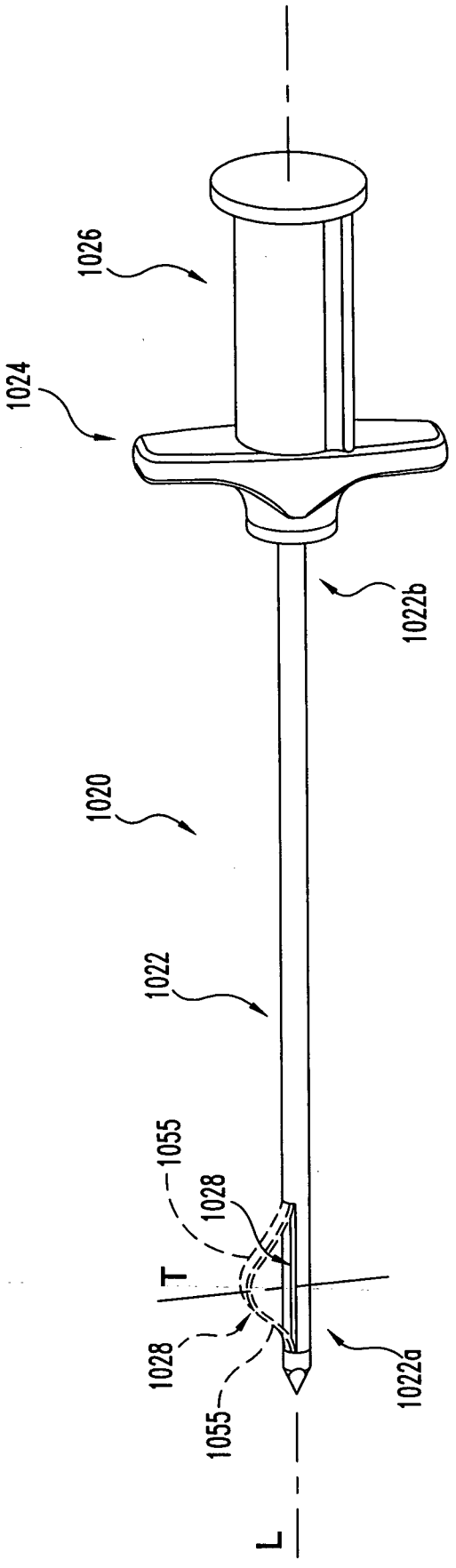
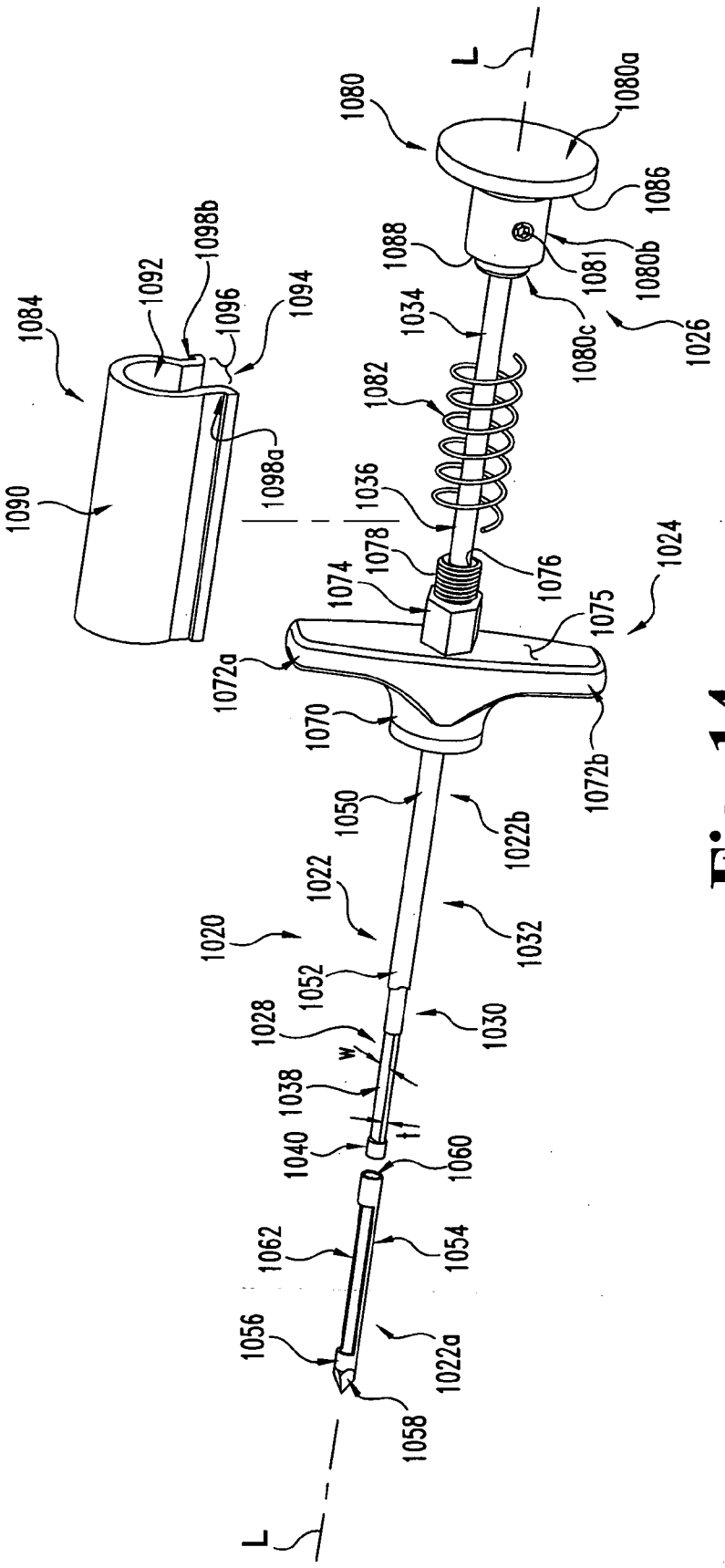


Fig. 13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1080b
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1070
1072b
1050
1022b
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1020
1052
1028
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T
1040
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1056
1022a
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L
1084
1092
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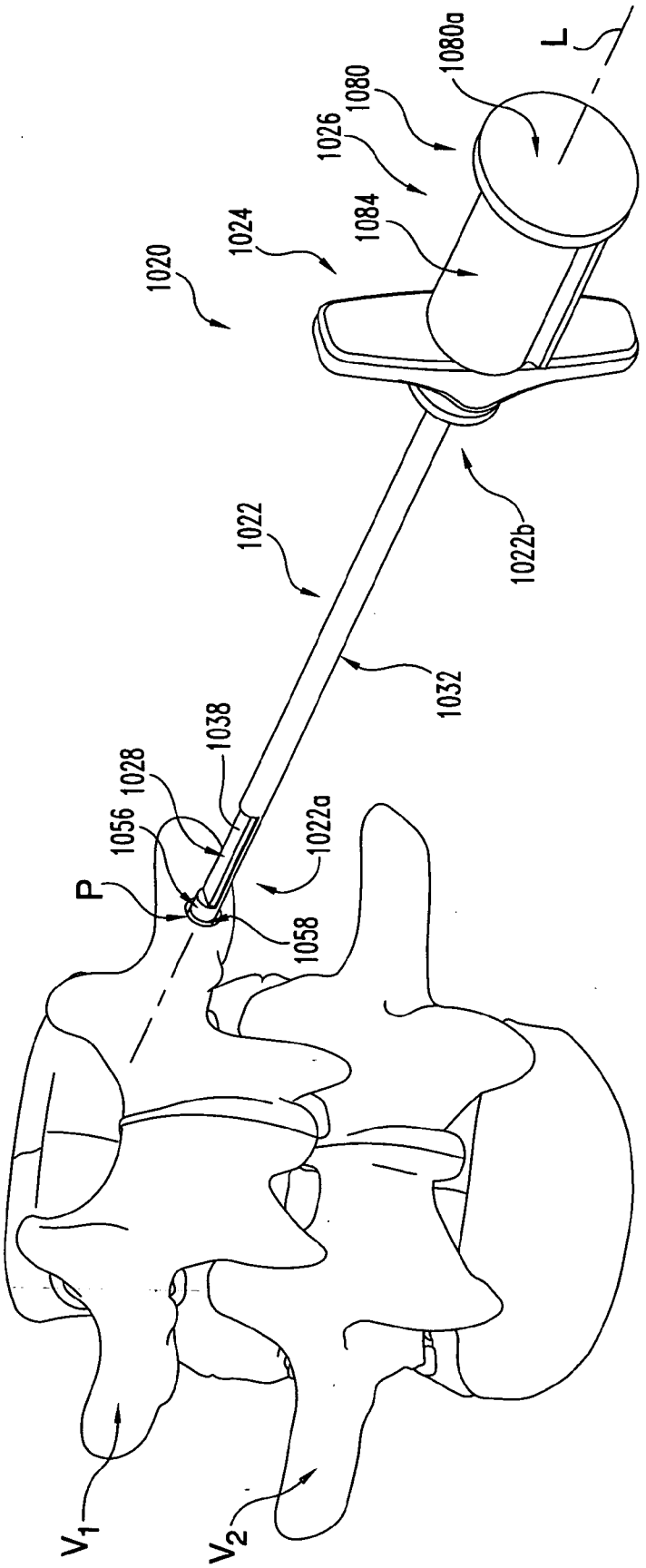
1090

Fig. 14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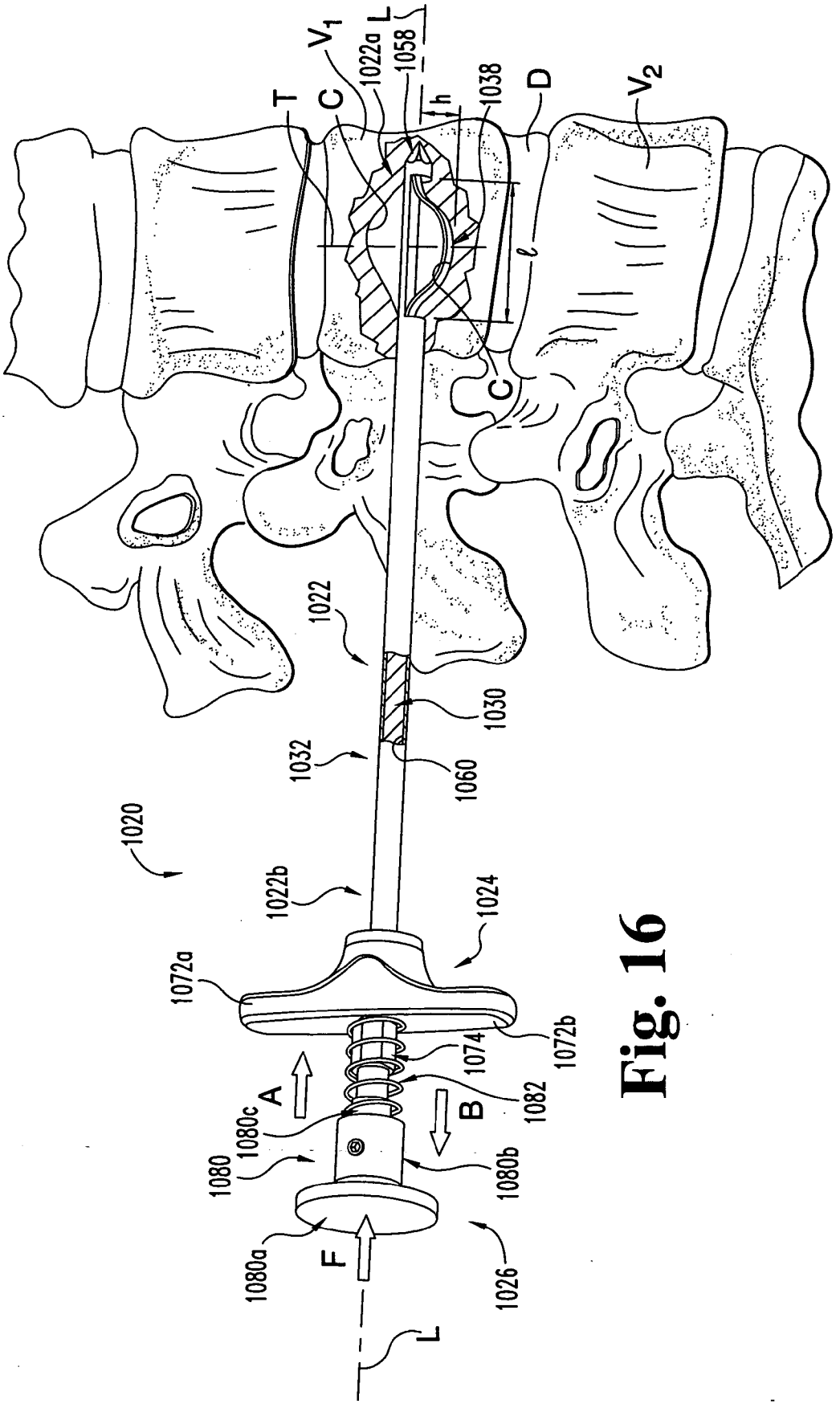
V_1
V_2

Fig. 15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1058
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D
V2
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1080a
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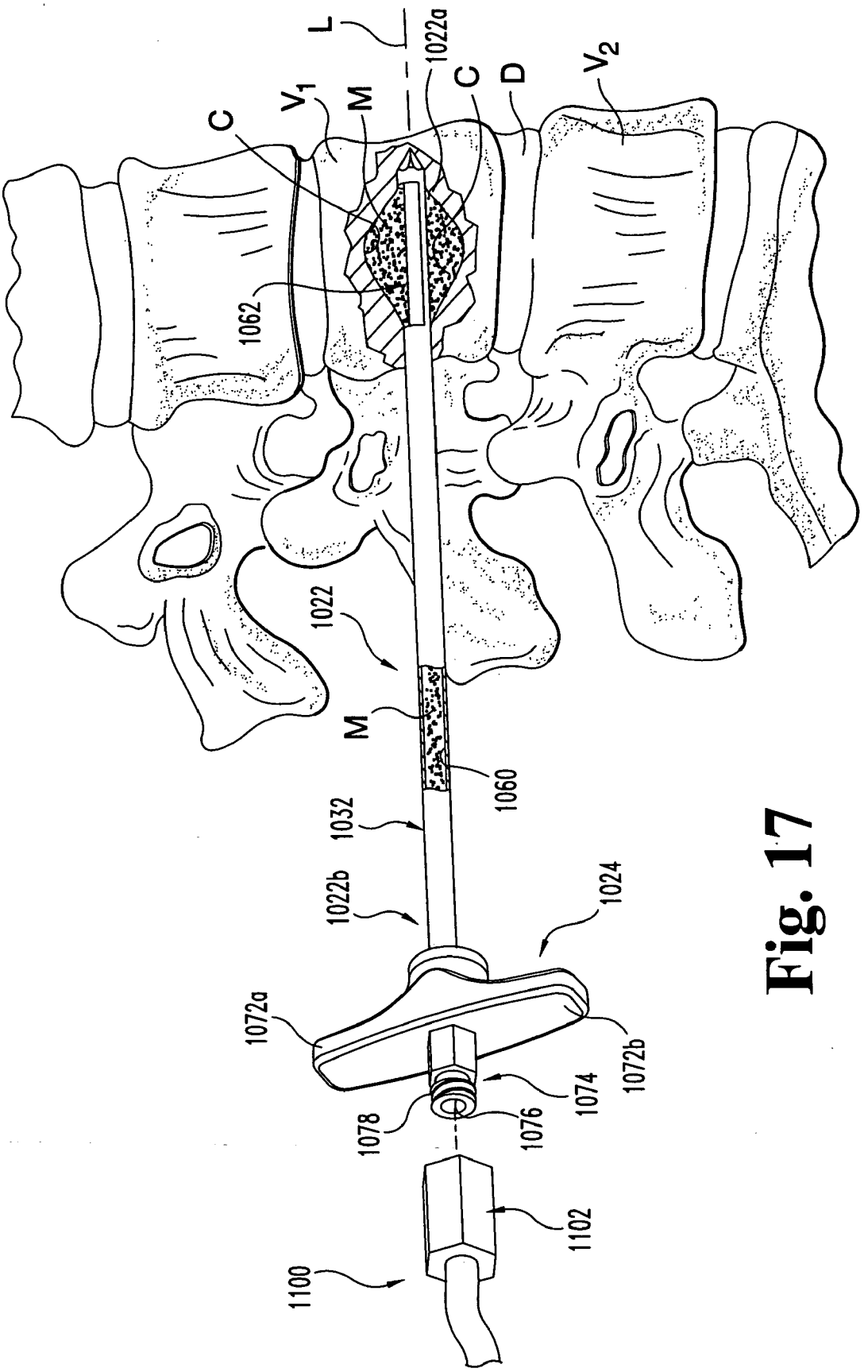
L

Fig. 16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V1
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Fig. 17

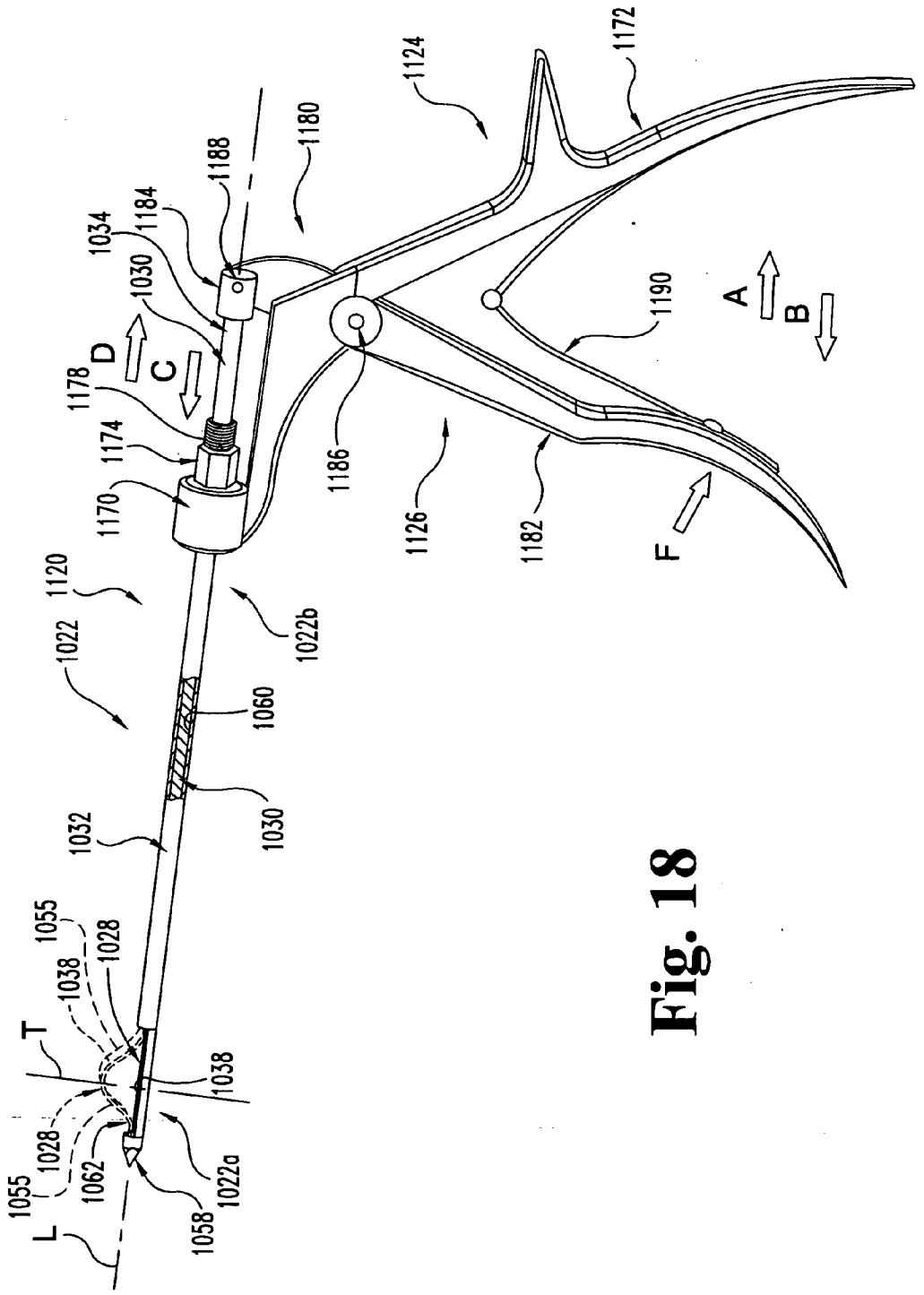
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Fig. 18

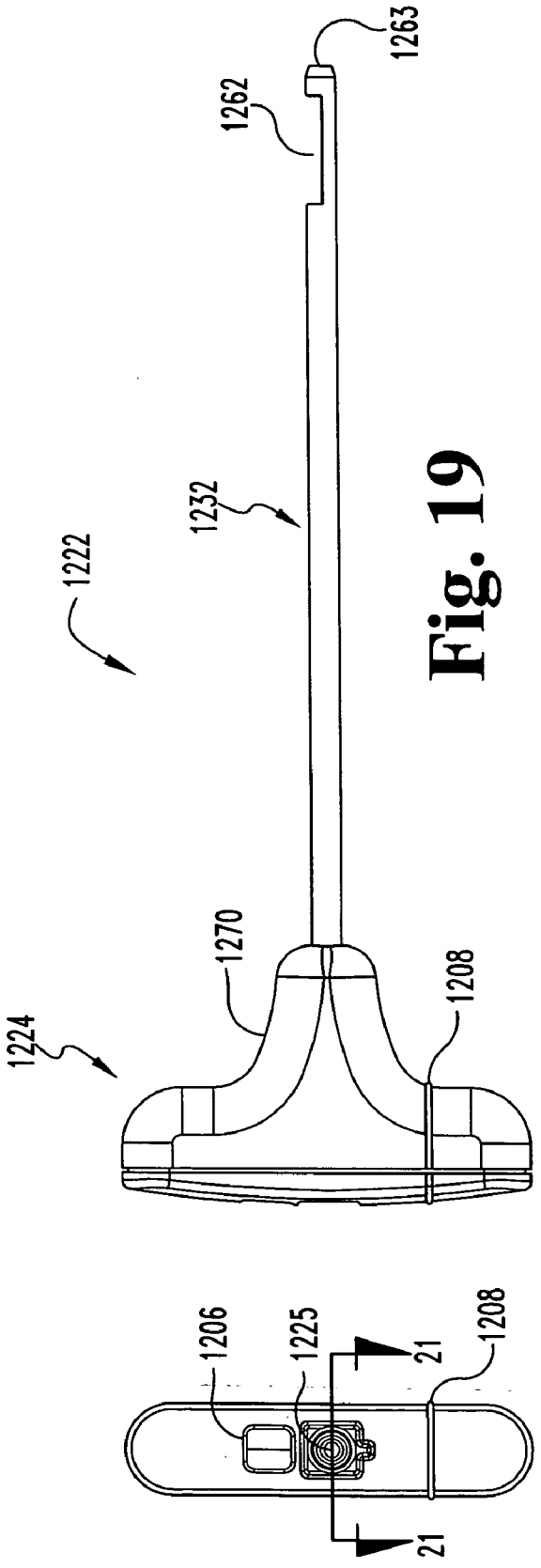

Fig. 19

Fig. 20

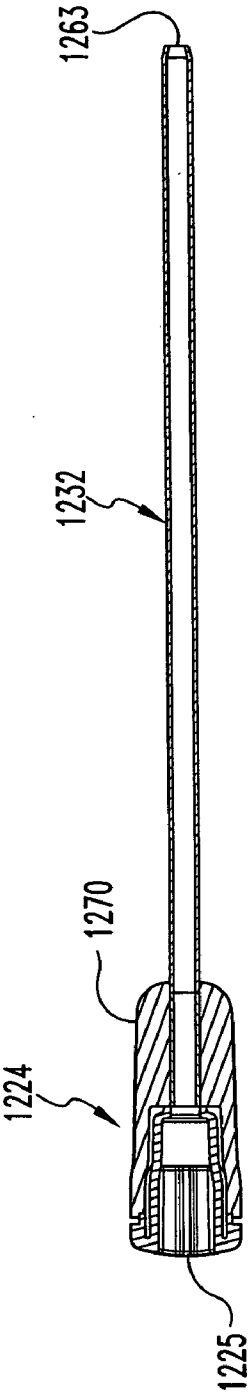

Fig. 21

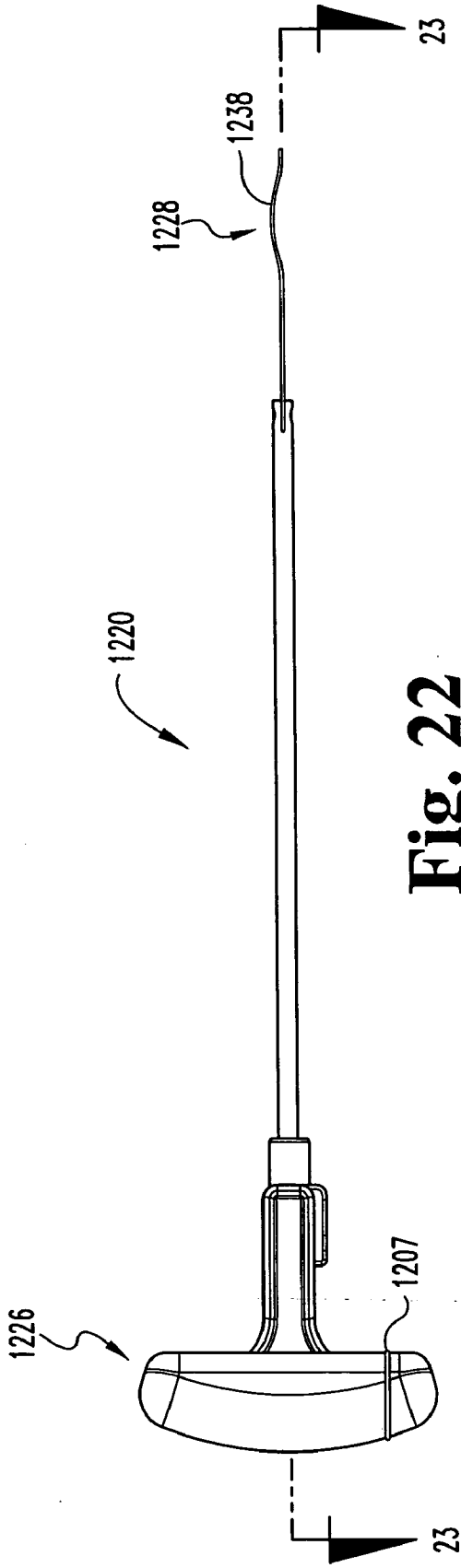

Fig. 22

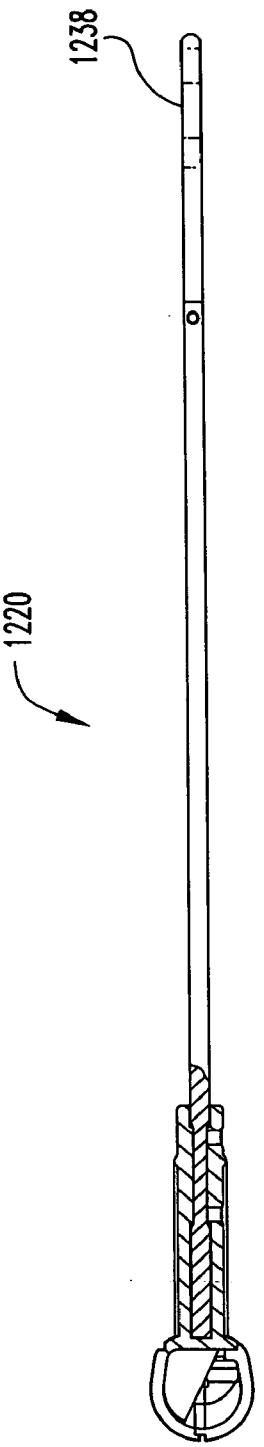

Fig. 23

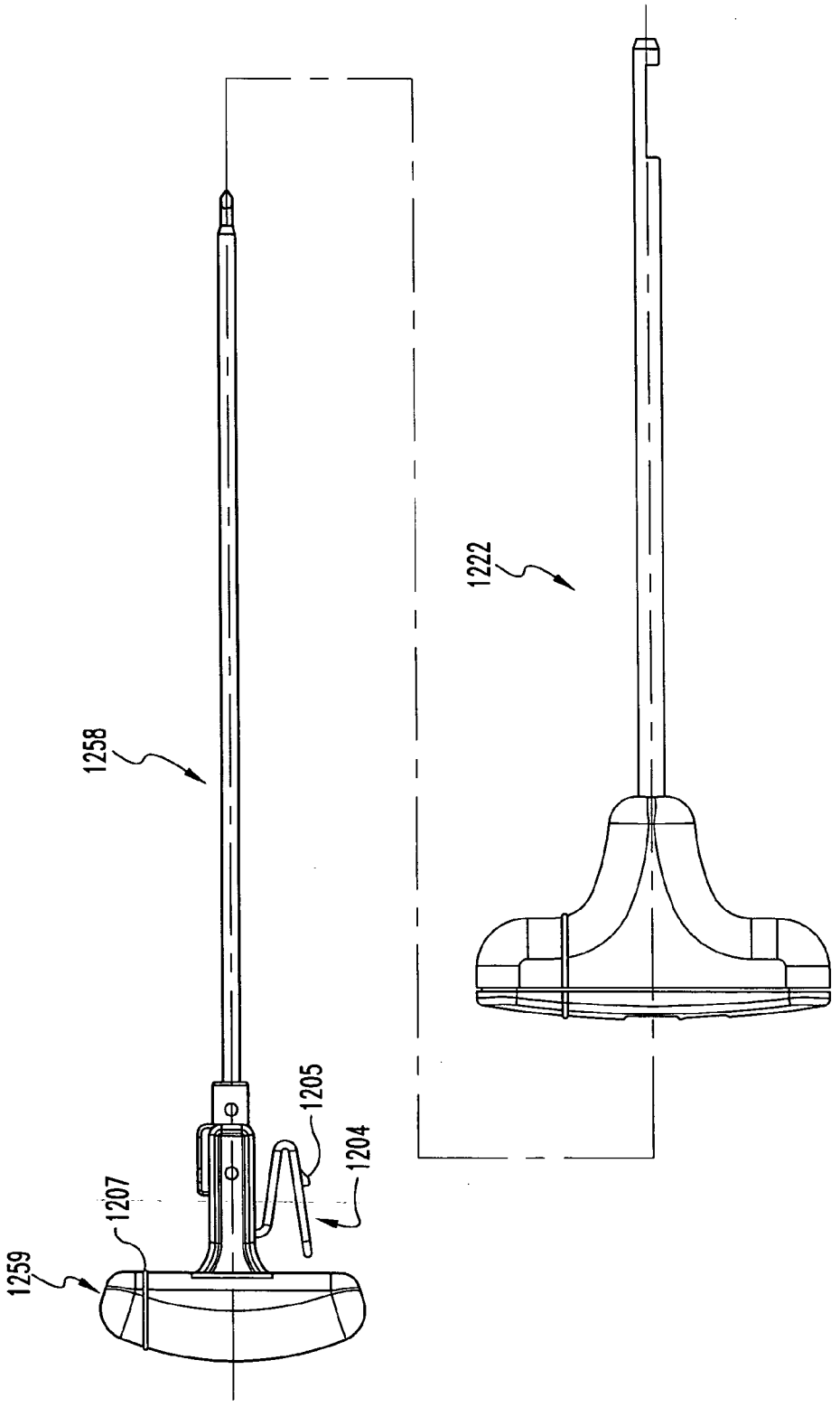

Fig. 24

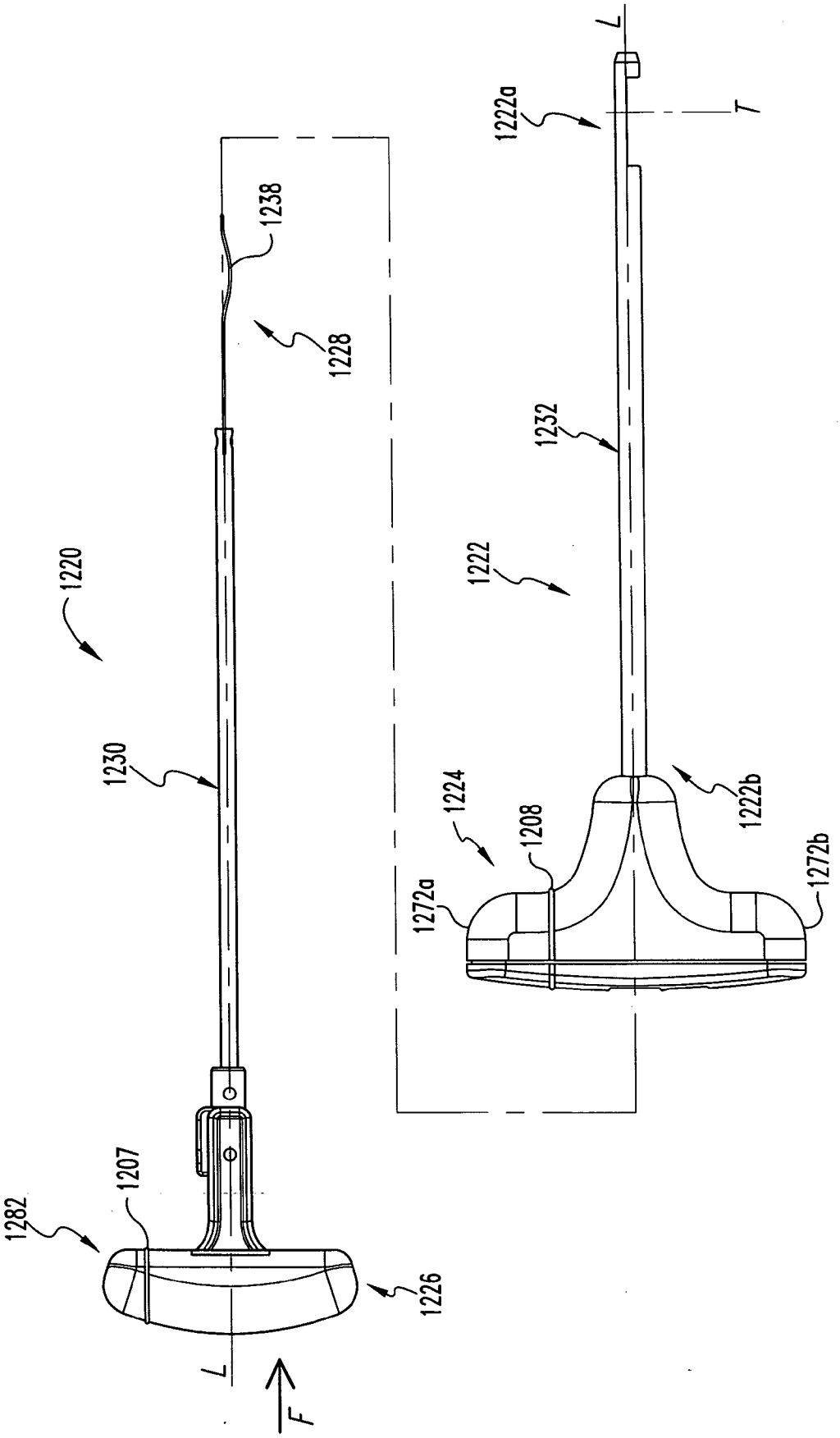
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Fig. 25

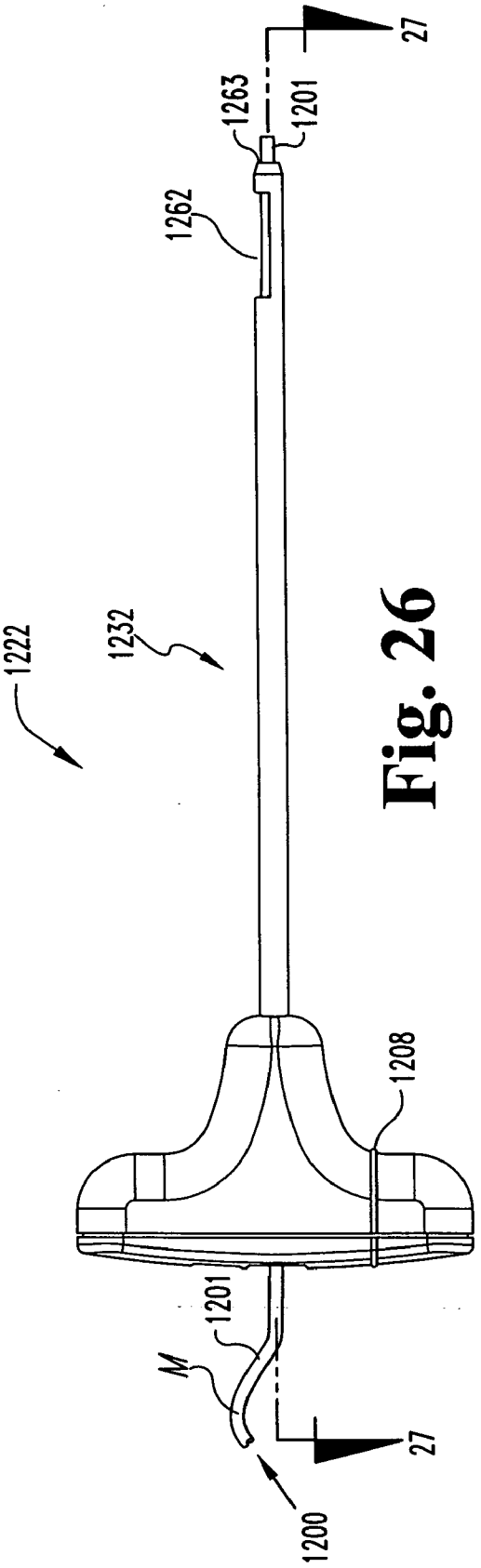
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Fig. 26

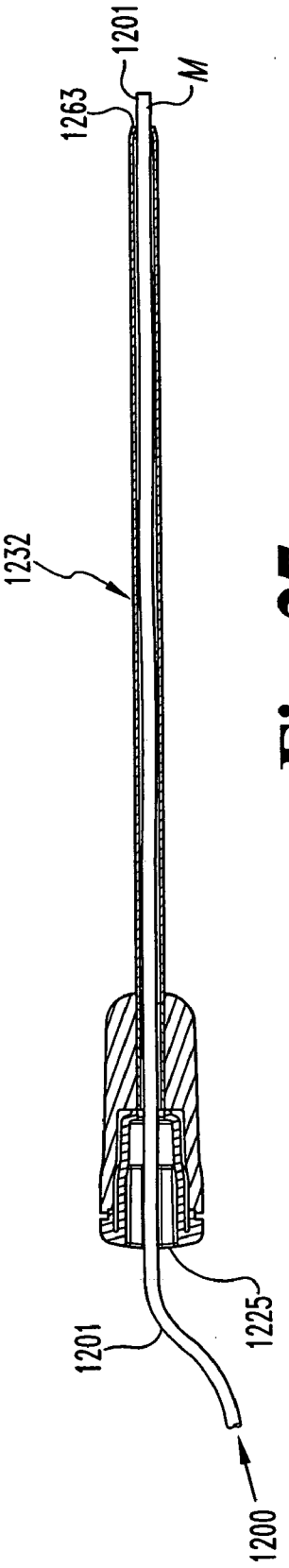
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Fig. 27

SURGICAL INSTRUMENTATION AND METHOD FOR TREATMENT OF A SPINAL STRUCTURE

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims the benefit of U.S. Provisional Patent Application Ser. No. 60/580,055 filed on Jun. 16, 2004, the contents of which are hereby incorporated by reference in their entirety.

TECHNICAL FIELD

[0002] The present invention relates generally to the field of surgical instrumentation and methods, and more particularly relates to instrumentation and methods for the repair of vertebral bodies and other orthopedic structures.

BACKGROUND

[0003] Various instruments and methods for the treatment of certain compression-type bone fractures and other osteoporotic and/or non-osteoporotic conditions have been developed. Such methods generally include a series of steps performed by a surgeon to correct and stabilize the compression fracture. In some cases, an access opening is formed in the bone to be treated followed by the insertion of an inflatable balloon-like device through the access opening and into an interior portion of the bone. Inflation of the balloon-like device may result in compaction of the bone marrow against the inner cortical wall of the bone, thereby resulting in the formation of a cavity in the bone and reduction of the compression fracture. The balloon-like device may then be deflated and removed from the bone. A biocompatible filling material, such as methylmethacrylate cement or a synthetic bone substitute, is sometimes delivered into the bone cavity and allowed to set to a hardened condition to provide internal structural support to the bone.

SUMMARY

[0004] An embodiment of the invention is a kit for treatment of the spine. The kit may include at least one cannula for maintaining a passageway to a portion of the spine to be treated and a surgical instrument for providing surgical access to the spine, the instrument being operable through the cannula. The kit of some embodiments also has a bone filler injector and a tube that provides a conduit between the bone filler injector and the cannula. The tube is extendable through the cannula to a position adjacent to the portion of the spine to be treated in some embodiments.

[0005] Yet another embodiment of the invention is a method of performing a biopsy with a medical instrument comprising a cannula member extending along a longitudinal axis and including a distal portion, with the cannula member defining an axial passage and a transverse opening positioned adjacent the distal portion and communicating with the axial passage, and an actuator member removably positioned within the axial passage of the cannula member and including a deformable portion positioned adjacent the transverse opening, and with the deformable portion being transitionable between an initial configuration for placement within a spinal structure and a deformed configuration defining a transverse projection extending through the transverse opening in the cannula member. Embodiments of the method also include selectively removing tissue on which a biopsy is to be accomplished from the cannula member.

[0006] Still another embodiment of the invention is a method for treatment of the spine. The method includes at least the acts of providing an instrument defining a cannula passage extending along a longitudinal axis and including a deformable distal portion having an insertion configuration and a deformed configuration, positioning the distal portion of the instrument within a spinal structure while in the insertion configuration, transitioning the distal portion of the instrument toward the deformed configuration while simultaneously rotating the instrument about the longitudinal axis to form a volume of loosened tissue within the spinal structure, and delivering a material through the cannula passage and into the spinal structure.

[0007] Another embodiment of the invention is a method for treatment of the spine, comprising providing an instrument defining a cannula passage extending along a longitudinal axis and including a deformable distal portion having an insertion configuration and a deformed configuration, and positioning the distal portion of the instrument within a spinal structure while in the insertion configuration. The instrument is activated to loosen tissue within the spinal structure. The method also includes removing a portion of the loosened tissue from the spinal structure, and delivering a material through the cannula passage and into the spinal structure.

[0008] Yet another embodiment of the invention is a method for treatment of the spine. The method includes at least the acts of providing an instrument defining a cannula passage extending along a longitudinal axis, positioning the distal portion of the instrument within a spinal structure while in the insertion configuration, and delivering a first portion of filler material through a tube extended through the cannula to a distal end of the accessible portion of the spinal structure. The tube is withdrawn proximally relative to the cannula and a second portion of filler material is delivered through the tube and into the spinal structure.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] **FIG. 1** is a perspective view of a surgical instrument according to one form of the present invention.

[0010] **FIG. 2** is an exploded side view of a distal end portion of the surgical instrument depicted in **FIG. 1**.

[0011] **FIG. 3** is an exploded side view of a proximal end portion of the surgical instrument depicted in **FIG. 1**.

[0012] **FIG. 4** is a broken cross-sectional side view of the surgical instrument depicted in **FIG. 1**.

[0013] **FIG. 5** is a perspective view of the distal end portion of the surgical instrument depicted in **FIG. 1**, as shown in an initial configuration.

[0014] **FIG. 6** is a perspective view of the distal end portion depicted in **FIG. 5**, as shown in a deformed configuration.

[0015] **FIG. 7** is a perspective view of the distal end portion of a surgical instrument according to another form of the present invention, as shown in an initial configuration.

[0016] **FIG. 8** is a perspective view of the distal end portion depicted in **FIG. 7**, as shown in a deformed configuration.

[0017] **FIG. 9** is a perspective view of the distal end portion of a surgical instrument according to another form of the present invention, as shown in an initial collapsed configuration.

[0018] **FIG. 10** is a perspective view of the distal end portion depicted in **FIG. 9**, as shown in a partially expanded configuration.

[0019] **FIG. 11** is a perspective view of the distal end portion depicted in **FIG. 9**, as shown in a fully expanded configuration.

[0020] **FIG. 12** is a partial cross-sectional side view of a spinal column illustrating treatment of a vertebral body using the surgical instrument illustrated in **FIG. 1**.

[0021] **FIG. 13** is a perspective view of a surgical instrument according to another form of the present invention.

[0022] **FIG. 14** is an exploded perspective view of the surgical instrument illustrated in **FIG. 13**.

[0023] **FIG. 15** is the surgical instrument illustrated in **FIG. 13**, as shown in an initial configuration for insertion of the distal portion of the instrument into a vertebral body.

[0024] **FIG. 16** is the surgical instrument illustrated in **FIG. 13**, as shown in an expanded configuration for forming a cavity within the vertebral body.

[0025] **FIG. 17** is the surgical instrument illustrated in **FIG. 13**, as shown in a delivery configuration for conveying a filling material into the cavity formed within the vertebral body.

[0026] **FIG. 18** is a perspective view of a surgical instrument according to another form of the present invention.

[0027] **FIG. 19** is a side view of a surgical instrument according to another form of the present invention.

[0028] **FIG. 20** is an end view of the proximal end of the surgical instrument illustrated in **FIG. 19**.

[0029] **FIG. 21** is a cross-sectional view of the surgical instrument illustrated in **FIG. 20**, as taken along line **21-21** of **FIG. 20**.

[0030] **FIG. 22** is a side view of a surgical instrument according to another form of the present invention.

[0031] **FIG. 23** is a partial cross-sectional view of the surgical instrument illustrated in **FIG. 22**, as taken along line **23-23** of **FIG. 22**.

[0032] **FIG. 24** is a partially exploded side view of a surgical instrument according to another form of the present invention.

[0033] **FIG. 25** is a partially exploded side view of a surgical instrument according to another form of the present invention.

[0034] **FIG. 26** is a side view of a surgical instrument according to another form of the present invention.

[0035] **FIG. 27** is a partial cross-sectional view of the surgical instrument illustrated in **FIG. 26**, as taken along line **27-27** of **FIG. 26**.

DESCRIPTION

[0036] Referring to **FIG. 1**, shown therein is an instrument **20** for treatment of the spine according to one form of the present invention. Instrument **20** is particularly useful for placement adjacent a spinal structure and selective displacement of at least a portion of the spinal structure. In one embodiment of the invention, the spinal structure is a vertebral body. It should be understood that instrument **20** may be used in intrabody applications such as, for example, a vertebroplasty procedure to compact cancellous bone within the vertebral body and/or to reduce a compression fracture of the vertebral body. Additionally, it should be understood that instrument **20** may be used in interbody applications such as, for example, to distract a space between adjacent vertebral bodies, such as the vertebral disc space. It should further be understood that in other embodiments of the invention, the spinal structure may be comprised of a spinal implant such as, for example, a cage device, or any other structure used in association with treatment of the spine. Additionally, although instrument **20** is illustrated and described in the context of treatment of a human spine, it should be understood that instrument **20** may be used to treat other animals. It should further be understood that instrument **20** may be used in association with applications outside of the spinal field such as, for example, to treat other types of bony structures.

[0037] Instrument **20** is generally comprised of an elongate member **22** extending generally along a longitudinal axis L and having a distal end portion **22***a* and a proximal end portion **22***b*. Although the illustrated embodiment depicts elongate member **22** as having a generally linear, unitary configuration, it should be understood that elongate member **22** may take on other configurations as well, such as, for example, a curvilinear configuration or a hinged configuration. Instrument **20** also includes an actuator mechanism **24** coupled to the proximal end portion **22***b* of elongate member **22**. As will be discussed in greater detail below, the distal end portion **22***a* is deformable and is configured to outwardly expand in response to a mechanically induced force. Such force may be effected, for example, by the selective actuation of actuator mechanism **24**.

[0038] As shown in **FIGS. 5 and 6**, the distal end portion **22***a* is reformable between an initial configuration (**FIG. 5**) and a deformed configuration (**FIG. 6**). As used herein, the term "initial configuration" is broadly defined to encompass a structural configuration of elongate member **22** that is suitable for placement adjacent a spinal structure, and the term "deformed configuration" is broadly defined to encompass a structural configuration of elongate member **22** that is suitable for preparation or displacement of at least a portion of the spinal structure. As discussed above, in one embodiment of the inventions the spinal structure is a vertebral body, and preparation of the vertebral body could be associated with either intrabody or interbody applications.

[0039] Referring to **FIG. 2**, shown therein are further details regarding the elongate member **22**, and more specifically the deformable distal end portion **22***a* of elongate member **22**. In one embodiment of the invention, the elongate member **22** is comprised of an inner rod member **30** and an outer sleeve member **32**. The illustrated embodiment of the inner rod **30** is formed of a substantially rigid medical

grade material such as, for example, titanium or stainless steel. The distal end portion **30***a* of rod **30** includes a tapered portion **34**, a reduced cross-section intermediate portion **36**, and a rounded distal end portion **38**. In one embodiment, the intermediate portion **36** has a diameter somewhat smaller than the diameter of the tapered portion **34** and the rounded distal end portion **38** so as to define a pair of opposing shoulders **40**, **42**. Although rod **30** has been illustrated and described as having a substantially circular cross section, it should be understood that other shapes and configurations are also contemplated as being within the scope of the invention including, for example, elliptical, square, rectangular or other polygonal configurations.

[**0040**] The outer sleeve **32** as illustrated has a tubular configuration defining an inner passage extending therethrough generally along longitudinal axis L and sized to slidably receive rod **30**. Sleeve **32** may be formed of a flexible material that is capable of facilitating deformation from an initial configuration toward a deformed configuration. Additionally, the sleeve **32** illustrated is formed of an elastic material that is capable of facilitating elastic deformation from the initial configuration toward the deformed configuration and reformation back toward the initial configuration. Sleeve **32** may be formed of materials including, but not limited to, titanium, stainless steel, an elastomer, a polymer, a rubber, a composite material or a shape-memory material. Although the entire length of sleeve **32** may be formed of a flexible, elastic material, it should be understood that only the distal end portion **32***a* of sleeve **32** need be formed of such material, with the remainder of sleeve **32** being formed of any suitable medical grade material. Moreover, although outer sleeve **32** is illustrated as having a substantially tubular configuration, it should be understood that other shapes and configurations of sleeve **32** are also contemplated as being within the scope of the present invention. Additionally, although sleeve **32** has been illustrated and described as being formed as a single-piece, unitary structure, it should be understood that the distal end portion **32***a* could be formed separately from the remainder of sleeve **32**, and coupled together by any known method, such as, for example, by fastening, welding or adhesion.

[**0041**] The distal end portion **32***a* of sleeve **32** includes at least one slot **50** extending generally along longitudinal axis L, and may include at least a pair of slots **50** and **52** (not shown) disposed generally opposite one another so as to define a pair of longitudinally extending flexible strips of material **54**, **56**. It should be understood, however, that the distal end portion **32***a* of sleeve **32** could be configured to define any number of longitudinally extending slots, including three or more slots, which would in turn define a corresponding number of longitudinally extending flexible strips of material. It should further be understood that distal end portion **32***a* may include a number of slots disposed at various axial locations along longitudinal axis L. As will be described below, the slots **50**, **52** are provided to facilitate outward buckling of the distal end portion **32***a* of sleeve **32** in at least one predetermined direction upon the selective actuation of the actuator mechanism **24**.

[**0042**] In the illustrated embodiment, the slots **50**, **52** are substantially identical in shape and configuration, and thus only slot **50** will be described in detail. However, it should be understood that slots **50**, **52** may take on different shapes and configurations. Slots **50**, **52** and strips of material **54**, **56** are illustrated as having a predetermined shape to provide a degree of control over the outward buckling of the strips of material **54**, **56**. In one embodiment of the invention, the slots **50**, **52** and strips of material **54**, **56** have an irregular shape. Slot **50** includes a relatively narrow and straight slot portion **60**, a first hourglass-shaped slot portion **62** formed by a first series of arcuate portions, and a second hourglass-shaped slot portion **64** formed by a second series of arcuate portions. As will become apparent below, the widened areas of the hourglass-shaped portions **62** and **64** serve as bending or flexion points to control the outward deformation of the flexible strips of material **54**, **56**.

[**0043**] The straight slot portion **60** extends longitudinally from the distal end of sleeve **32**. The first hourglass-shaped portion **62** extends longitudinally from slot portion **60** and includes a first widened area **62***a*, a narrowed area **62***b*, and a second widened area **62***c*. The second hourglass-shaped portion **64** extends longitudinally from the first hourglass-shaped portion **62** and includes a first widened area **64***a*, a narrow area **64***b*, and a second widened area **64***c*. Although a specific configuration of slots **50**, **52** have been illustrated and described, it should be understood that other shapes and configuration of slots **50**, **52** are also contemplated as falling within the scope of the invention.

[**0044**] In one embodiment of the invention, the distal end portion **32***a* of sleeve **32** is secured to the inner rod **30** by way of a compression ring **70**. Specifically, the distal-most portion of sleeve **32** is disposed about portion **36** of rod **30**, with the distal end of sleeve **32** abutting the shoulder **42** formed by the rounded distal end portion **38**. The compression ring **70** is positioned about the distal-most portion of sleeve **32** and is compressed thereabout, such as, for example, by mechanical crimping to secure sleeve **32** to inner rod **30**. As should be appreciated, slot portion **60** aids in tightly compressing sleeve **32** about inner rod **30** to provide secure engagement therebetween. It should be understood that compression ring **70** could alternatively be compressed about distal-most portion of sleeve **32** by other means, such as, for example, by forming compression ring **70** out of a shape-memory material that is reformable to a memorized configuration having an internal diameter that is less than the outer diameter of sleeve **32**. It should further be understood that the distal-most end portion of sleeve **32** could be secured to rod **30** by other means, such as, for example, by fastening, welding, adhesion or other methods of attachment known to those of skill in the art.

[**0045**] Referring to **FIGS. 3 and 4**, shown therein are further details regarding the actuator mechanism **24**. Actuator mechanism **24** is generally comprised of a rotary handle **100**, a stationary handle **102**, a connector assembly **104**, and an actuator member **106**. As will be discussed in further detail below, the connector assembly **104** is configured to secure the elongate member **22**, and more specifically the outer sleeve **32**, to the remainder of the actuator mechanism **24**. As will also be discussed below, the threaded actuator member **106** is coupled to the inner rod **30** and is engaged with the rotary handle **100** such that rotational displacement of handle **100** about longitudinal axis L linearly displaces the actuator member **106** along longitudinal axis L. As described above, the linear displacement of rod **30** relative to sleeve **32** causes the distal end portion **32***a* of sleeve **32** to reform from its initial configuration toward its deformed configuration.

[0046] The rotary handle **100** includes a pair of lateral extensions **110**, **112** extending outwardly from a main body portion **114** to define a T-handle arrangement which aids the surgeon in rotating the handle **100** relative to the stationary handle **102**. The main body portion **114** includes an opening extending along longitudinal axis L and having a threaded portion **116** and an unthreaded portion **118**. A hub portion **120** extends from the main body portion **114** and defines an annular groove **122**.

[0047] The stationary handle **102** includes a pair lateral extensions **130**, **132** extending outwardly from a main body portion **134** to define a second T-handle arrangement which aids the surgeon in securely gripping instrument **20** and in maintaining the handle **102** in a stationary rotational position during rotation of handle **100**. The main body portion **134** includes an opening extending therethrough along longitudinal axis L and defining a first cavity **136** and a second cavity **138**. A pair of openings **140**, **142** extend through the main body portion **134** and are disposed in communication with the first cavity **136**. The hub portion **120** of handle **100** is inserted within the first cavity **136** and a pin or fastener **148** is inserted through opening **140** and positioned within the annular groove **122** to axially couple rotary handle **100** to stationary handle **102** while permitting relative rotational displacement therebetween.

[0048] The actuator member **106** includes a threaded shank portion **150** and an unthreaded shank portion **152**. The threaded shank portion **150** is configured to threadingly engage the threaded opening **116** in rotary handle **100**. In one embodiment of the invention, the threaded shank portion **150** and the threaded opening **116** each define right hand threads. The unthreaded shank portion **152** includes a slotted opening **154** extending therethrough that is aligned with the opening **142** in the stationary handle **102**. A pin or fastener **155** is inserted through the opening **142** and the slotted opening **154** to couple the actuator member **106** to the stationary handle **102**. As should be apparent, pin **155** substantially prevents relative rotational displacement between actuator member **106** and handle **102** while allowing a limited amount of relative linear displacement along longitudinal axis L. The distal end portion of the actuator member **106** includes a socket **156** configured to accept a corresponding ball portion **158** extending from the proximal end portion **30***b* of rod **30**. The socket opening **156** includes a spherical portion **160** sized to receive the ball portion **158** therein, and a cylindrical portion **162** sized to receive the distal end portion **30***b* of rod **30** therethrough to connect rod **30** to actuator member **106**. It should be understood, however, that other methods of interconnecting rod **30** and actuator member **106** are also contemplated as would occur to one of skill in the art.

[0049] As discussed above, the connector assembly **104** is configured to connect the elongate member **22**, and more specifically the outer sleeve **32**, to the remainder of the actuator mechanism **24**. The connector assembly **104** is generally comprised of a gripper member **170**, a lock collar member **172** and a biasing member **174**. The gripper member **170** includes a connecting segment **176**, a gripping segment **178** and a longitudinal passage having a first portion **180** extending through connecting segment **176** and a second portion **181** extending through the gripping segment **178**. The first portion **180** of the passage is sized to receive the shank portion **152** of actuator member **150** therein, and the second portion **181** of the passage is sized to receive the proximal end portion **32***b* of sleeve **32** therein.

[0050] The gripping segment **178** of gripper member **170** has a generally conical shape and includes a tapered outer surface **182**. The gripping segment **178** also includes a longitudinally extending slit **183** and a pair of transverse slots **184** that intersect slit **183**, with both the slit **183** and the slots **184** intersecting the longitudinal passage **181**. One purpose of the slit **183** and the slots **184** is to facilitate compression of the gripping segment **178** about the proximal end portion **32***b* of sleeve **32**. The proximal end portion **32***b* of sleeve **32** defines an opening or window **185** extending therethrough to further facilitate gripping of sleeve **32** by gripping segment **178**. Another purpose of slit **183** is to provide a passageway for the lateral insertion of the proximal end portion **30***b* of rod **30** therethrough to permit assembly with the actuator member **106**. The gripping segment **178** also includes an outer tapered surface **186**, the purpose of which will become evident below.

[0051] The connecting segment **176** of gripper member **170** defines an elongate opening **187** extending transversely therethrough and being positioned in communication with the longitudinal slit **183**. One purpose of the elongate opening **187** is to facilitate compression of the gripping segment **178** about the proximal end portion **32***b* of sleeve **32**. Another purpose of the transverse slot **187** is to provide a passageway for the lateral insertion of the ball portion **158** of rod **30** therethrough and into engagement with the socket **156** defined in actuator member **106**. The connecting segment **176** also includes an opening **188** extending transversely therethrough and aligned with the opening **142** in the stationary handle **102**. Pin **155** is inserted through the opening **188** to axially couple the gripper member **170**, and in turn the elongate member **22**, to the stationary handle **102** in a manner that substantially prevents relative linear and rotational displacement therebetween.

[0052] The lock collar member **172** includes a cylindrically-shaped body portion **190**, a tapered end portion **192**, and a longitudinal passage **194** extending therethrough and being sized to receive the connecting segment **176** of gripper member **170** therein. The cylindrical body portion **190** is sized to be received within cavity **138** of stationary handle **102**. The longitudinal passage **194** includes an inner tapered surface **196** that corresponds to the outer tapered surface **186** of gripping segment **178**. In one embodiment of the invention, the biasing member **174** is a coil spring. However, it should be understood that other types of biasing devices may alternatively be used as would occur to one of skill in the art.

[0053] Referring to **FIG. 4**, spring **174** is disposed within the cavity **138** of stationary handle **102** and is engaged against the proximal end of the lock collar **172** to bias the lock collar **172** toward the gripping segment **178**. The biasing of lock collar **172** engages the tapered inner surface **196** tightly against the tapered outer surface **186** of gripping segment **178**. Such engagement creates an inward compression force onto the gripping segment **178**, which in turn causes the gripping segment **178** to collapse tightly about the proximal end portion **32***b* of sleeve **32** to securely grip sleeve **32** within the longitudinal passage **181**. The tapered outer surface **192** of lock collar **172** is oriented at about the same angle as the tapered outer surface **182** of gripping segment **178** to provide a relatively smooth transition between lock collar **172** and gripping segment **178**.

[0054] Based on the above description and corresponding illustrations, it should be apparent that rotation of handle **100** relative to stationary handle **102** in a clockwise direction (assuming right hand threading) will cause the actuator member **106** to be linearly displaced in the direction of arrow A, which will correspondingly cause rod **30** to be linearly displaced in the direction of arrow A. Furthermore, since the distal end portion of sleeve **32** is engaged with the distal end portion of rod **30**, linear displacement of rod **30** in the direction of arrow A will cause the deformable distal end portion **32***a* of sleeve **32** to buckle outwardly toward the deformed configuration illustrated in **FIG. 6**. It should also be apparent that rotation of handle **100** relative to stationary handle **102** in a counter-clockwise direction will cause the actuator member **106** to be linearly displaced in the direction of arrow B, which will correspondingly cause rod **30** to be linearly displaced in the direction of arrow B. Linear displacement of rod **30** in the direction of arrow B will cause the deformable distal end portion **32***a* of sleeve **32** to reform back toward the insertion configuration illustrated in **FIG. 5**. As should be apparent, instead of rotating handle **100** relative to handle **102** to impart relative linear displacement between rod **30** and sleeve **32**, it is also possible to hold handle **100** in a stationary position and to rotate handle **102** relative to handle **100** to impart relative linear displacement between rod **30** and sleeve **32**.

[0055] Although one specific embodiment of the actuator mechanism **24** has been illustrated and described herein, it should be understood that the use of other types and configurations of actuator mechanisms are also contemplated as would occur to one of skill in the art. As should be apparent, any type of actuator mechanism that is capable of imparting relative displacement between rod **30** and sleeve **32** to reform the distal end portion **32***a* of sleeve **32** between the initial and deformed configurations may be used. It should further be understood that in an alternative form of the invention, rod **30** may be manually displaced by the surgeon relative to sleeve **32**, thereby eliminating the need for a separate actuator mechanism **24**.

[0056] Referring now to **FIGS. 5 and 6**, shown therein is the distal end portion **22***a* of elongate member **22**, as shown in an initial insertion configuration and a mechanically deformed expanded configuration, respectively. When in the initial configuration (**FIG. 5**), the distal end portion **32***a* of sleeve **32** has a relatively low profile to facilitate positioning adjacent a vertebral body. As should be appreciated, the rounded distal end portion **38** reduces the likelihood of damage to adjacent tissue during such positioning. As used herein, positioning of the distal end portion **32***a* adjacent a vertebral body is meant to include positioning of the distal end portion **32***a* in proximity to a vertebral body, within a vertebral body or within a space between adjacent vertebral bodies. As discussed above, instrument **20** may also be used in association with spinal structures other than a vertebral body, such as, for example, a spinal implant, with the distal end portion **32***a* of sleeve **32** being positioned adjacent or within the spinal implant when in the insertion configuration.

[0057] Once properly positioned adjacent the vertebral body, the distal end portion **32***a* of sleeve **32** is mechanically deformed by displacing the rod **30** relative to the sleeve **32**. In the illustrated embodiment of the invention, such relative displacement is accomplished by linearly displacing rod **30** relative to sleeve **32** in the direction of arrow A, and is initiated by the selective actuation of actuator mechanism **24**. In an alternative embodiment of the invention, the distal end portion **32***a* of sleeve **32** may be mechanically deformed toward the expanded configuration by way of relative rotational displacement between rod **30** and sleeve **32**.

[0058] When reformed toward the expanded configuration (**FIG. 6**), the distal end portion **32***a* of sleeve **32** is outwardly deformed relative to longitudinal axis L so as to form a number of laterally extending projections or protrusions **198***a*, **198***b*. As discussed above, the deformed configuration of instrument **20** may define any number of laterally extending projections, including a single projection or three or more projections, and may define a number of laterally extending projections at various axial locations along longitudinal axis L. It should be apparent that the number, position, and direction of the laterally extending projections is at least partially controlled by the configuration and placement of the slots **50** in sleeve **32**. In this manner, formation of the laterally extending projections and the resulting preparation of the vertebral body is said to be directionally controlled. Moreover, if the deformed configuration of instrument **20** defines a single projection **198***a*, or a single pair of opposing projections **198***a*, **198***b* aligned along a common transverse axis T, then formation of the laterally extending projection and the resulting preparation of the vertebral body is said to be uniaxial. Further, if the deformed configuration of instrument **20** defines a single projection **198***a* extending in a single direction, then formation of the laterally extending projection and the resulting preparation of the vertebral body is said to be unidirectional.

[0059] Following preparation of the vertebral body, the distal end portion **32***a* of sleeve **32** may be reformed from its deformed/expanded configuration back toward its initial insertion configuration by linearly displacing rod **30** relative to sleeve **32** in the direction of arrow B. As discussed above, the distal end portion **32***a* of sleeve **32** may be formed of a shape-memory material, such as, for example, a shape-memory alloy ("SMA") to aid in reforming the distal end portion **32***a* from the deformed configuration back toward its initial configuration. More specifically, SMAs are known to exhibit a characteristic or behavior in which a particular component formed of an SMA is capable of being deformed from an initial "memorized" shape or configuration to a different shape or configuration, and then reformed back toward its initial shape or configuration.

[0060] Further details regarding the superelastic phenomena of a SMA and additional characteristics of stress-induced martensite are more fully described by Yuichi Suzuki in an article entitled Shape Memory Effect and Super-Elasticity in Ni—Ti Alloys, Titanium and Zirconium, Vol. 30, No. 4, October 1982, the contents of which are hereby incorporated by reference. Additionally, while there are many alloys that exhibit shape-memory or superelastic characteristics, one of the more common SMAs is an alloy of nickel and titanium. One such well-known SMA is Nitinol. It should be understood, however, that other SMA materials that exhibit superelastic characteristics are contemplated as being within the scope of the invention.

[0061] If the distal end portion **32***a* of outer sleeve **32** is formed of an SMA material and is reshaped or deformed while at a temperature above the transformation temperature

A, of the SMA, the distal end portion **32***a* will automatically recover or reform toward its initial shape or configuration when the stress is removed from distal end portion **32***a*. As illustrated in **FIG. 5**, when distal end portion **32***a* is in its unstressed initial configuration, virtually all of the SMA material will be in an austenitic state. However, upon the imposition of stress onto distal end portion **32***a* (e.g., by turning actuator handle **100** in a clockwise direction relative to stationary handle **102**), at least a portion of the SMA material will transform into reversible stress-induced martensite as the distal end portion **32***a* is deformed toward the expanded configuration. Upon the reduction or removal of the stress (e.g., by turning actuator handle **100** in a counter clockwise direction), at least a portion of the SMA material will be transformed back into austenite and the distal end portion **32***a* will automatically reform back toward the initial configuration.

[**0062**] In some embodiments of the invention, the projections **198***a*, **198***b* may be designed to provide a cutting edge **55** that is exposed to cut tissue when the projections **198***a*, **198***b* are extended. The cutting edge **55** may be a thin portion of the sleeve **32**, or in some embodiments may be sharpened to an edge that is significantly thinner than the thickness of the sleeve **32** to provide a sharper cutting edge. The cutting edge **55** may be tempered, serrated, or otherwise treated or configured to enhance the ability of the projections to cut through tissue, as is known in the art of tissue cutting devices.

[**0063**] Referring now to **FIGS. 7 and 8**, shown therein is the distal end portion of an instrument **200** according to another form of the present invention, as shown in an initial insertion configuration and a mechanically deformed configuration, respectively. It should be understood that instrument **200** may be used in association with applications similar to those discussed above with regard to instrument **20**, including both intrabody and interbody applications involving preparation or displacement of at least a portion of a vertebral body.

[**0064**] Instrument **200** is generally comprised of an elongate member **222** extending along a longitudinal axis L and having a distal end portion (as shown) and a proximal end portion (not shown) coupled to an actuator mechanism which may be configured similar to actuator mechanism **24**. The distal end portion of elongate member **222** is deformable and is configured to outwardly expand in response to a mechanically induced force. Specifically, the distal end portion is reformable between an initial configuration (**FIG. 7**) for positioning adjacent a vertebral body, and a deformed configuration (**FIG. 8**) for preparation of at least a portion of the vertebral body. Although the illustrated embodiment depicts elongate member **222** as having a generally linear, unitary configuration, it should be understood that elongate member **222** may take on other configurations as well, such as, for example, a curvilinear configuration or a hinged configuration.

[**0065**] In the illustrated embodiment of instrument **200**, the elongate member **222** is generally comprised of an inner rod member **230** and an outer sleeve member **232**. The inner rod **230** may be formed of a substantially rigid medical grade material such as, for example, titanium or stainless steel. The rod **230** includes a distal end portion **230***a* that is disposed within and coupled to a distal end portion **232***a* of sleeve **232**. Although rod **230** has been illustrated and described as having a substantially circular cross, it should be understood that other shapes and configurations are also contemplated as being within the scope of the present invention, such as, for example, elliptical, square, rectangular or other polygonal configurations.

[**0066**] The outer sleeve **232** illustrated has a tubular configuration defining an inner passage extending therethrough generally along longitudinal axis L and sized to slidably receive rod **230** therein. Sleeve **232** is formed of a relatively flexible material that is capable of being reformed from an initial configuration to an expanded configuration. The sleeve **232** may be formed of a relatively elastic material that is capable of being elastically deformed to the expanded configuration and reformed back toward the initial configuration. Sleeve **232** may be formed of materials including, but not limited to, titanium, stainless steel, an elastomer, a polymer, a rubber, a composite material or a shape-memory material. Although the entire length of sleeve **232** may be formed of a flexible, elastic material, it should be understood that only the distal end portion **232***a* need be formed of such material, with the remainder of sleeve **232** being formed of any suitable medical grade material. Additionally, although sleeve **232** is illustrated as having a substantially cylindrical or tubular configuration, it should be understood that other shapes and configurations of sleeve **232** are also contemplated as being within the scope of the present invention. Furthermore, although sleeve **232** has been illustrated and described as being formed as a single-piece, unitary structure, it should be understood that the distal end portion **232***a* could be formed separately from the remainder of sleeve **232**, and coupled together by any known method, such as, for example, by fastening, welding or adhesion.

[**0067**] In one embodiment of instrument **200**, the distalmost end portion **270** of sleeve **232** is secured to the distal end portion **230***a* of rod **230** by way of crimping. In other embodiments, sleeve portion **270** may be connected to rod portion **230***a* by a compression ring similar to compression ring **70**, or by other connection techniques such as, for example, fastening, welding, adhesion, or other methods of attachment known to those of skill in the art.

[**0068**] The distal end portion **232***a* of sleeve **232** includes at least one rectangular-shaped window or slot **250** extending generally along longitudinal axis L, and may include at least a pair of slots **250** and **252** (not shown) disposed generally opposite one another so as to define a pair of longitudinally extending flexible strips of material **254**, **256**. However, it should be understood that the distal end portion **232***a* of sleeve **232** could define any number of longitudinally extending slots, including three or more slots, which would in turn define a corresponding number of flexible strips of material disposed between the slots. The slots **250**, **252** are provided to facilitate outward buckling of the distal end portion **232***a* of sleeve **232** upon the imposition of relative linear displacement between rod **230** and sleeve **232**. As illustrated in **FIG. 8**, when reformed toward the expanded configuration, the flexible strips of material **254**, **256** will outwardly buckle along transverse axis T at a location adjacent the midpoint of slots **250**, **252**. In the illustrated embodiment of instrument **200**, the slots **250**, **252** are substantially identical in shape and configuration. However, it should be understood that slots **250**, **252** may take on different predetermined shapes and configurations. Addi-

tionally, although slots **250**, **252** and strips of material **254**, **256** are illustrated as having a generally rectangular shape, other predetermined shapes and configurations are also contemplated.

[**0069**] When in the initial configuration (**FIG. 7**), the distal end portion **232***a* of sleeve **232** has a relatively low profile to facilitate positioning adjacent a vertebral body. However, once properly positioned adjacent the vertebral body, the distal end portion **232***a* is mechanically deformed by displacing rod **230** relative to sleeve **232**. In the illustrated embodiment, such relative displacement is accomplished by linearly displacing rod **230** relative to sleeve **232** in the direction of arrow A. In an alternative form of the present invention, the distal end portion **232***a* of sleeve **232** may be mechanically deformed toward the expanded configuration by way of relative rotational displacement between rod **230** and sleeve **232**.

[**0070**] When reformed toward the expanded configuration (**FIG. 8**), the distal end portion **232***a* of sleeve **232** is outwardly deformed relative to longitudinal axis L so as to form a number of laterally extending projections or protrusions **298***a*, **298***b*. As discussed above, the deformed/expanded configuration of instrument **200** may alternatively define any number of laterally extending projections, including a single projection or three or more projections. Similar to instrument **20**, formation of the laterally extending projections and the resulting preparation of the vertebral body by instrument **200** is directionally-controlled, and can be uniaxial, unidirectional or both uniaxial and unidirectional. Following preparation of the vertebral body, the distal end portion **232***a* of sleeve **232** may be reformed back toward its initial insertion configuration by linearly displacing rod **230** relative to sleeve **232** in the direction of arrow B. As discussed above with regard to instrument **20**, the distal end portion **232***a* of sleeve **232** may be formed of a shape-memory material, such as, for example, a shape-memory alloy to aid in reforming distal end portion **232***a* back toward its initial configuration.

[**0071**] In some embodiments of the invention, the projections **298***a*, **298***b* may be designed to provide a cutting edge **255** that is exposed to cut tissue when the projections **298***a*, **298***b* are extended. The cutting edge **255** may be a thin portion of the sleeve **232**, or in some embodiments may be sharpened to an edge that is significantly thinner than the thickness of the sleeve **232** to provide a sharper cutting edge. The cutting edge may be tempered, serrated, or otherwise treated or configured to enhance the ability of the projections to cut through tissue, as is known in the art of tissue cutting devices.

[**0072**] In one embodiment of the invention, at least the distal end portion of the elongate member **222** is covered by a flexible membrane **280**. The flexible membrane **280** may be formed of a resilient material that is capable of conforming to the shape of the distal end portion **232***a* of sleeve **232** during reformation between the initial and deformed configurations. Such flexible materials include, but are not limited to, silicone, latex, rubber, a polymer or other suitable elastomeric materials. One purpose of the flexible membrane **280** is to prevent tissue or other foreign material from passing through the slots **250**, **252** and being deposited within the space between the strips of material **254**, **256** and the rod **230** and/or between the rod **230** and the remainder of the sleeve **232**. As should be appreciated, such a build-up of tissue or foreign material may block or otherwise inhibit reformation of the distal end portion **232***a* of sleeve **232** from the deformed configuration (**FIG. 8**) back toward the initial configuration (**FIG. 7**). Although the flexible membrane **280** is illustrated as covering the distal end portion of elongate member **222**, it should be understood that the flexible membrane **280** could be sized to cover the entire length of the elongate member **222**. It should also be understood that a flexible membrane similar to flexible membrane **280** may be used in association with the surgical instrument **20** discussed above and/or the surgical instrument **300** discussed below.

[**0073**] Referring now to **FIGS. 9-11**, shown therein is the distal end portion of an instrument **300** according to another form of the present invention, as shown in an initial insertion configuration, a partially deformed intermediate configuration, and a fully deformed configuration, respectively. It should be understood that instrument **300** may be used in association with applications similar to those discussed above with regard to instrument **20**, including both intrabody and interbody applications involving preparation or displacement of at least a portion of a vertebral body.

[**0074**] Instrument **300** is comprised of an elongate member **322** extending generally along a longitudinal axis L and having a distal end portion (as shown) and a proximal end portion (not shown) which may be coupled to an actuator mechanism similar to actuator mechanism. The distal end portion is deformable and is configured to outwardly expand upon the imposition of a mechanically induced force. Specifically, the distal end portion is reformable between an initial configuration (**FIG. 9**) for positioning adjacent a vertebral body, and a deformed configuration (**FIG. 11**) for preparation of at least a portion of the vertebral body. Although the illustrated embodiment depicts elongate member **322** as having a generally linear, unitary configuration, it should be understood that elongate member **322** may take on other configurations as well, such as, for example, a curvilinear configuration or a hinged configuration.

[**0075**] In the illustrated embodiment of instrument **300**, the elongate member **322** is generally comprised of an inner rod member **330** and an outer sleeve member **332**. The inner rod **330** may be formed of a substantially rigid medical grade material such as, for example, titanium or stainless steel. Rod **330** includes a distal end portion **330***a* extending from a main body portion **330***b*. In the illustrated embodiment, the distal end portion **330***a* has a rectangular shape and the main body portion **330***b* has a square shape. However, it should be understood that other shapes and configurations of rod **330** are also contemplated as being within the scope of the present invention such as, for example, circular, elliptical or polygonal configurations.

[**0076**] The outer sleeve **332** has a deformable distal end portion **332***a* coupled to a main body portion **332***b*. The main body portion **332***b* has a square configuration defining an inner passage extending therethrough generally along longitudinal axis L and sized to slidably receive portion **330***b* of rod **330** therein. However, it should be understood that other shapes and configurations of sleeve portion **332***b* are also contemplated as being within the scope of the present invention. The main body portion **332***b* shown is formed of

a substantially rigid material, such as, for example, titanium, stainless steel or other substantially rigid medical grade materials.

[0077] The deformable distal end portion **332***a* of sleeve **332** is at least partially formed of a relatively flexible material that is capable of being reformed from the initial configuration illustrated in **FIG. 9** toward the deformed configuration illustrated in **FIG. 11**. In some embodiments, the distal end portion **332***b* is formed of a relatively elastic material that is capable of being elastically deformed toward the deformed configuration and reformed back toward the initial configuration. The deformable distal end portion **332***b* may be formed of materials including, but not limited to, titanium, stainless steel, an elastomer, a polymer, a rubber, a composite material or a shape-memory material. Distal end portion **332***b* shown is formed separately from main body portion **332***a* and connected thereto by any method know to one of skill in the art, such as, for example, by fastening, welding or adhesion. However, is should be understood that distal end portion **332***b* could alternatively be formed integral with main body portion **332***a* to define a single-piece, unitary structure.

[0078] The deformable distal end portion **332***a* of sleeve **332** includes a plurality of wall elements **354-357** that are flexibly interconnected by a number or interconnection portions **360**. In one embodiment of the invention, the interconnection portions **360** are defined by forming an opening or channel **362** at locations where adjacent wall elements adjoin to one another. In one embodiment of the invention, the wall elements **354-357** are integrally formed to define a unitary, single-piece reformable structure that is collapsible to define a relatively low-profile insertion configuration and expandable to define an outwardly deformed configuration.

[0079] To aid in reformation of the distal end portion **332***a* between the insertion and deformed configurations, the distal end portion **332***a* of sleeve **332** may be flexibly coupled to the main body portion **332***b*. In one embodiment, the outer wall elements **354**, **355** each include a flexible interconnection portion **366** defined by forming an opening or channel **367** adjacent their respective distal end portions **354***a*, **355***a*. The distal end portions **354***a*, **355***a* of the outer wall elements **354**, **355** are in turn coupled to inner surfaces of the main body portion **332***b* of sleeve **332**, such as, for example, by fastening, welding or adhesion. The outer wall elements **354**, **355** are separated by a distance sufficient to receive the distal end portion **330***a* of rod **330** therebetween.

[0080] As shown in **FIG. 9**, the insertion configuration has a substantially rectangular-shaped profile, with each of the wall elements **354-357** being disposed in a substantially uniform orientation (i.e., parallel to one another), and with the two inner wall elements **356**, **357** being disposed between the two outer wall elements **354**, **355**. As shown in **FIG. 11**, the deformed/expanded configuration has a substantially triangular-shaped profile, with the two inner wall elements **356**, **357** being disposed in a substantially parallel and co-linear orientation, and the two outer wall elements **354**, **355** being disposed at an angle e relative to inner wall elements **356**, **357**. In one embodiment, the angle θ is about 30°-45°. It should be understood that other insertion and expanded configurations are also contemplated as falling within the scope of the present invention. Additionally, although the reformable distal end portion **332***b* of sleeve **332** has been illustrated and described as including four wall elements **354-357**, it should be understood that any number of wall elements may be flexibly interconnected to form the refofrmable distal end portion **332***b*.

[0081] When in the initial folded configuration illustrated in **FIG. 9**, the deformable distal end portion **332***a* of sleeve **332** has a relatively low profile to facilitate positioning adjacent a vertebral body. However, once properly positioned adjacent the vertebral body, the distal end portion **332***a* is mechanically deformed by displacing rod **330** relative to sleeve **332**. In the illustrated embodiment, such relative displacement is accomplished by linearly displacing rod **330** relative to sleeve **332** in the direction of arrow B, and is initiated by the selective actuation of an actuator mechanism (not shown).

[0082] As shown in **FIG. 10**, relative displacement of rod **330** in the direction of arrow B causes the distal end portion **330***a* of rod **330** to engage the interconnection portion **360** extending between the inner wall elements **356**, **357**, thereby initiating the outward expansion or unfolding of the wall elements **354-357**. In one embodiment of the invention, the distal end portion **330***a* of rod **330** is secured to the interconnection portion **360**, such as, for example, by fastening, welding or adhesion. However, it should be understood that the distal end portion **330***a* of rod **330** need not necessarily be rigidly secured to interconnection portion **360**, but could alternatively form an abutting relationship therewith to initiate the outward expansion of wall elements **354-357**.

[0083] As shown in **FIG. 11**, when reformed to the deformed configuration, the wall elements **354-357** are unfolded and expanded outwardly relative to longitudinal axis L so as to form laterally extending projections or protrusions **398***a*, **398***b* disposed along a transverse axis T. Although instrument **300** has been illustrated and described as including a pair of oppositely disposed projections **398***a*, **398***b* when in the expanded configuration, it should be understood that the distal end portion **332***a* of sleeve **332** may be configured to define any number of projections, including a single projection or three or more projections. Further, similar to instrument **20**, the expansion of the distal end portion **332***a* of sleeve **332** and the resulting preparation of the spinal structure accomplished by instrument **300** is directionally-controlled, and can be uniaxial, unidirectional or both uniaxial and unidirectional.

[0084] In some embodiments of the invention, the wall elements **354-357** may be designed to provide cutting edges **455** that are exposed to cut tissue when the wall elements **354-357** are extended. The cutting edges **455** may be essentially the same thickness as wall elements **354-357**, or in some embodiments may be sharpened to an edge that is significantly thinner than the thickness of the wall elements **354-357** to provide a sharper cutting edge. The cutting edge may be tempered, serrated, or otherwise treated or configured to enhance the ability of the projections to cut through tissue, as is known in the art of tissue cutting devices.

[0085] Following preparation of the vertebral body, the distal end portion **332***a* of sleeve **332** may be reformed toward its initial insertion configuration by linearly displacing rod **330** relative to sleeve **332** in the direction of arrow A (**FIG. 11**). As discussed above with regard to instrument **20**, the distal end portion **332***a* of sleeve **332** may be formed

of a shape-memory material, such as, for example, a shape-memory alloy ("SMA") to aid in reforming distal end portion **332***a* back toward its initial configuration.

[**0086**] Referring to **FIG. 12**, shown therein is a lateral view of a spinal column, illustrating the introduction and expansion of instrument **20** within a vertebral body V_1 to perform intrabody distraction. The distal end portion **32***a* of sleeve **30** is initially passed through an access opening (not shown) extending through an outer wall of the vertebral body V_1 while in the undeformed initial configuration illustrated in **FIG. 5**. Subsequent to insertion within the vertebral body V_1, the distal end portion **32***a* of sleeve **32** is reformed by a mechanically-induced force created by linearly displacing rod **30** relative to sleeve **32** in the direction of arrow A. As a result, the distal end portion **32***a* is outwardly deformed to form opposing projections **198***a*, **198***b* extending along transverse axis T. Such outward deformation is particularly useful, for example, to compact or compress cancellous bone against the inner cortical wall of the vertebral body V_1 to form a cavity C therein. Compaction of the cancellous bone may have the effect of exerting an outward force on the inner surface of the cortical wall, making it possible to elevate or push broken and/or compressed bone back to or near its original pre-fracture condition or another desired condition. Alternatively, the opposing projections **198***a*, **198***b* may bear directly against the inner surface of the cortical bone to reduce a compression fracture in the vertebral body V_1.

[**0087**] In one form of the present invention, access into the inner cancellous region of the vertebral body V_1 is be accomplished by drilling a relatively small access opening through an outer wall of the vertebral body, such as, for example, through the pedicular region of the vertebral body V_1. The undeformed initial configuration of the distal end portion **32***a* of sleeve **30** is sized to pass through the small access opening to gain access to the inner cancellous region of the vertebral body V_1. In this manner, insertion of the distal end portion **32***a* of sleeve **32** is accomplished in a minimally invasive manner. Additionally, unlike certain prior art devices that require a relatively larger access opening to accommodate spreading of the proximal end portions of opposing members attached to one another in a scissors-like manner, only the distal end portion **32***a* of sleeve **32** is outwardly expanded when reformed toward the deformed configuration.

[**0088**] In one embodiment of the invention, the initial configuration of the distal end portion **32***a* of sleeve **32** is sized to pass through an access opening having a diameter between about 1 millimeter and about 5 millimeters. In a specific embodiment, the initial configuration of the distal end portion **32***a* is sized to pass through an access opening having a diameter of about 3 millimeters. In another embodiment of the invention, the deformed configuration of the distal end portion **32***a* of sleeve **30** is sized to displace the vertebral body V_1 within a range of about 3 millimeters to about 15 millimeters. In a specific embodiment, the deformed configuration of the distal end portion **32***a* is sized to displace the vertebral body V_1 about 10 millimeters. In another specific embodiment of the invention, the instrument **20** is capable of assuming a deformed configuration that is over three times greater than its initial configuration. Although ranges and specific sizes of the initial and deformed configurations of distal end potion **32***b* of sleeve **32** have been set forth above, it should be understood that such ranges and specific sizes are exemplary and are not intended to limit the scope of the present invention in any manner whatsoever.

[**0089**] Following preparation of the vertebral body V_1, the distal end portion **32***a* of sleeve **32** is reformed toward its initial insertion configuration by displacing rod **30** relative to sleeve **32** in the direction of arrow B. As a result, the opposing projections **198***a*, **198***b* are inwardly deformed to the extent necessary to provide uninhibited removal of the distal end portion **32***a* of sleeve **32** from the vertebral body V_1. As discussed above, reformation of the instrument **20** back toward its initial insertion configuration may be facilitated by forming the distal end portion **32***a* of sleeve **32** from a shape-memory material. Following the removal of instrument **20** from the vertebral body V_1, the cavity C may be filled with a biocompatible filling material, such as, for example, methylmethacrylate cement (e.g., bone cement), a structural implant, and/or a therapeutic substance to promote healing. Once set to a hardened condition, the filling material provides internal structural support to the vertebral body V_1, and more particularly provides structural support to the cortical bone of the vertebral body V_1.

[**0090**] In another form of the present invention, a cannula assembly **400** may be used to provide minimally invasive access to the vertebral bodies V_1, V_2 and/or the disc space D. As shown in **FIG. 12**, use of the cannula assembly **400** permits preparation of the vertebral body V_1 via insertion and manipulation of instrument **20** through a single working channel. Further details regarding a cannula assembly suitable for use in association with the present invention are disclosed in U.S. Pat. No. 6,599,291 to Foley et al., filed on Oct. 20, 2000, the contents of which are incorporated herein by reference.

[**0091**] The cannula assembly **400** includes a cannula **402** having a distal end **402***a* and defining an inner working channel **404** extending between the distal end **402***a* and a proximal end (not shown). The length of the cannula **402** is sized such that the proximal end (not shown) of the cannula **402** is positioned beyond the skin of the patient when the distal end **402***a* is positioned adjacent the vertebral body V_1. One advantageous feature of the cannula assembly **400** is the relatively large cross section of the working channel **404** extending through cannula **402**. Such a large cross section permits the surgeon to introduce a wide variety of instruments or tools into the working channel **404**, as well as the simultaneous introduction of two or more instruments or tools. Furthermore, the relatively large cross section of working channel **404** permits a wide range of motion of the instruments and tools.

[**0092**] The cannula assembly **400** may also include an endoscope assembly (not shown) mounted to the proximal end portion of the cannula **402** to provide remote visualization of the surgical site. The endoscope assembly may include, for example, a viewing element **406** disposed within the working channel **404** of cannula **402** and having a distal end **406***a* positioned adjacent the surgical site. The viewing element **406** in some embodiments is linearly and rotatably displaceable within the working channel **404** to provide a wide degree of visualization of the surgical site. The endoscope assembly may also include an illumination element (not shown), a remote viewing apparatus such as an eyepiece

(not shown), and/or irrigation and aspiration components (not shown) extending along viewing element **406**. One embodiment of an endoscope assembly suitable for use in association with the present invention is described in U.S. Pat. No. 6,152,871 to Foley et al., issued on Nov. 28, 2000, the contents of which are incorporated herein by reference. The cannula assembly **400** may also include a microscopic viewing system (not shown) mounted to the proximal end portion of the cannula **402** to provide microscopic visualization of the surgical site. One embodiment of a microscopic viewing system suitable for use in association with the present invention is described in U.S. Pat. No. 6,679,833 to Foley et al., filed on Mar. 23, 2001, the contents of which are incorporated herein by reference.

[**0093**] Although **FIG. 12** illustrates the use of instrument **20** to at least partially displace the vertebral body V_1, it should be understood that instruments **200** and **300** could alternatively be used to perform the technique. It should also be understood that in addition to performing intrabody distraction, instruments **20**, **200** and **300** may be used to perform interbody distraction of one or both of the adjacent vertebral bodies V_1, V_2, such as, for example, to increase the height of the disc space D. Interbody distraction of adjacent vertebral bodies V_1, V_2 may also be effective to increase the distance between corresponding portions of the vertebral bodies V_1, V_2. In cases involving brittle portions of the vertebral bodies V_1, V_2, shims may be positioned between the deformable distal end portion **32***a* of sleeve **32** and the vertebral bodies V_1, V_2 to distribute the compressive force over a larger area to avoid puncturing or crushing of the brittle portions. It should additionally be understood that although the distraction technique illustrated in **FIG. 12** uses a posterior surgical approach, other surgical approaches are also contemplated, such as, for example, anterior, lateral, and postero-lateral approaches.

[**0094**] Referring to **FIG. 13**, shown therein is another embodiment of an instrument **1020** for treatment of the spine according to one form of the present invention. The illustrated instrument **1020** is designed for planned disposal upon use in association with a limited number of surgical procedures. In a specific embodiment, the instrument **1020** is designed for a single use in association with a single surgical procedure. In instances where the instrument **1020** is designed for a single use, immediate disposal eliminates the requirements and costs associated with cleaning, sterilizing, repackaging, and/or storing the instrument **1020** for repeat use. However, it should be understood that the instrument **1020** may be designed for use in association with multiple surgical procedures or may be designed to have a predetermined life span for use in association with a predetermined number of spinal surgeries after which the instrument **1020** is subjected to disposal. The instrument **1020** is generally comprised of an elongate member **1022**, a handle portion **1024**, an actuator mechanism **1026**, and a deformable portion **1028** that is selectively transitionable between an initial configuration (shown in solid lines) and a deformed configuration (shown in phantom lines).

[**0095**] The elongate member **1022** extends generally along a longitudinal axis L and has a distal portion **1022***a* and a proximal portion **1022***b*. Although the illustrated embodiment depicts the elongate member **1022** as having a generally linear, unitary configuration, it should be understood that elongate member **1022** may take on other configurations such as, for example, a curvilinear configuration or a hinged configuration. The handle portion **1024** aids in the manipulation and handling of the instrument **1020** and also includes a mechanism for connecting to a material delivery system, the detail of which will be discussed below. The actuator mechanism **1026** serves to transition the deformable portion **1028** between the initial and deformed configurations. The deformable portion **1028** is located adjacent the distal portion **1022***a* of the elongate member **1022** and outwardly expands along a transverse axis T in response to a mechanically induced force that is provided via selective actuation of the actuator mechanism **1026**.

[**0096**] Referring to **FIG. 14**, shown therein is an exploded view of the instrument **1020** which illustrates additional elements and features associated with the elongate member **1022**, the handled portion **1024**, the actuator mechanism **1026** and the deformable portion **1028**. Each of these components will now be discussed in greater detail.

[**0097**] In one embodiment of the invention, the elongate member **1022** is generally comprised of an inner rod member **1030** and an outer sleeve member **1032**. The inner rod **1030** includes a proximal end portion **1034**, a main body portion **1036**, a deformable distal portion **1038** (comprising the deformable portion **1028**), and a distal end portion **1040**. In one embodiment, the inner rod **1030** is formed as a single-piece, unitary structure. However, it should be understood that portions of the inner rod **1030** (such as the deformable portion **1038** and/or the distal end portion **1040**) could be formed separately and coupled together by any known method such as by fastening, welding or adhesion.

[**0098**] In the illustrated embodiment, the proximal end portion **1034**, the main body portion **1036** and the distal end portion **1040** have a generally circular outer cross section that substantially corresponds to the inner cross section of the outer sleeve **1032**. However, it should be understood that other shapes and configurations are also contemplated as falling within the scope of the invention including, for example, elliptical, square, rectangular, hexagonal, or other arcuate or polygonal configurations. In the illustrated embodiment, the deformable portion **1038** comprises a relatively thin, flexible strip of material extending generally along the longitudinal axis L. In a specific embodiment, the deformable strip **1038** comprises a generally flat, spring-like element to facilitate transitioning between a relatively straight initial configuration and an outwardly deformed or buckled configuration. However, it should be understood that other suitable configurations of the deformable strip **1038** are also contemplated to facilitate transitioning between an initial configuration and an outwardly deformed configuration.

[**0099**] The inner rod **1030** may be formed of a medical grade material such as, for example, titanium or stainless steel. However, it should be understood that the inner rod **1030** may be formed of other suitable medical grade materials. For example, in one embodiment, the deformable strip **1038** may be formed of a flexible material that is capable of facilitating elastic deformation from the initial configuration toward the deformed configuration and reformation back toward the initial configuration. In a specific embodiment, at least the deformable strip **1038** is formed of a thin metallic material such as titanium or stainless steel, an elastomeric material, a polymeric material, a rubber material, a compos-

ite material, or any other suitable flexible material to facilitate transitioning of the deformable strip **1038** between the initial and deformed configurations. In another specific embodiment, at least the deformable strip **1038** may be formed of a shape-memory material exhibiting superelastic characteristics to facilitate transitioning of the deformable strip **1038** from the initial configuration to the deformed configurations and reformation back toward the initial configuration. For example, at least the deformable strip **1038** may be formed of a shape-memory alloy ("SMA") such as, for example, Nitinol. As should be appreciated, the width, thickness, shape and/or cross section of the deformable strip **1038** have an effect on the deformation characteristics and each provide a degree of control over the outward deformation/buckling of the deformable strip **1038**. Although the deformable strip **1038** is illustrated as having a having a generally rectangular axial cross section defining a substantially uniform width w, it should be understood that the deformable strip **1038** may define a non-uniform width w. For example, in an alternative embodiment, the deformable portion may define one or more cut-ins or grooves along its axial length. In a specific embodiment, the deformable strip **1038** may be configured to have an hour-glass configuration to provide predetermined deformation characteristics associated with outward expansion of the deformable strip **1038** along the transverse axis T. As should be appreciated, segments of the deformable strip **1038** having a reduced width w would tend to provide less resistance to bending and serve as flexion points to facilitate outward deformation/buckling adjacent the areas of reduced width. Additionally, although the deformable strip **1038** is illustrated as having a having a substantially uniform thickness t, it should be understood that the deformable strip **1038** may define a non-uniform thickness t to provide predetermined deformation characteristics associated with outward expansion of the deformable strip **1038** along the transverse axis T. As should be appreciated, segments of the deformable portion **1038** having a reduced thickness t would tend to provide less resistance to bending and would thereby facilitate outward buckling adjacent the areas of reduced thickness.

[**0100**] In some embodiments of the invention, the deformable strip **1038** may be designed to provide a cutting edge **1055** that is exposed to cut tissue when the deformable strip **1038** is extended. The cutting edge **1055** may be a thin portion of the deformable strip **1038**, or in some embodiments may be sharpened to an edge that is significantly thinner than the thickness t of the deformable strip **1038** to provide a sharper cutting edge. The cutting edge may be tempered, serrated, or otherwise treated or configured to enhance the ability of the projections to cut through tissue, as is known in the art of tissue cutting devices.

[**0101**] In the illustrated embodiment of the invention, the inner rod **1030** includes a single deformable strip **1038** extending along the longitudinal axis L which is configured to outwardly deform/buckle in a single direction along the transverse axis T so as to provide controlled unidirectional expansion. However, it should be understood that in other embodiments of the invention, the inner rod **1030** may include two or more deformable strips of material **1038** extending along the longitudinal axis L which are configured to outwardly deform/buckle in multiple directions. In a specific embodiment, such outward deformation of the multiple strips of material would be limited to expansion along the transverse axis T so as to provide controlled uniaxial expansion.

[**0102**] The outer sleeve **1032** generally includes a proximal end portion **1050**, a main body portion **1052**, a distal portion **1054**, and a distal end portion **1056**. In the illustrated embodiment, the proximal end portion **1050** of the sleeve **1032** extends axially from the handle portion **1024** and the distal end portion **1056** defines a pointed tip or trocar **1058** to facilitate insertion into and/or through vertebral tissue. However, other configurations of the distal end portion **1056** are also contemplated such as, for example, configurations defining a blunt or rounded tip to provide non-traumatic passage through vertebral tissue. The outer sleeve **1032** shown is formed of a substantially rigid medical grade material such as, for example, titanium or stainless steel. However, it should be understood that the outer sleeve **1032** may be formed of other suitable medical grade materials.

[**0103**] In the illustrated embodiment of the invention, the outer sleeve **1032** has a tubular configuration defining an axial cannula passage **1060** extending generally along the longitudinal axis L and sized to slidably receive the inner rod **1030** therein, the purpose of which will be discussed below. In one embodiment, the cannula passage **1060** has a generally circular inner cross section substantially corresponding to the outer cross section of the main body portion **1036** and distal end portion **1040** of the inner rod **1030**. However, it should be understood that other shapes and configurations are also contemplated as falling within the scope of the invention including, for example, elliptical, square, rectangular, hexagonal or other arcuate or polygonal configurations. Additionally, although the outer sleeve **1032** is illustrated as being formed as a single-piece, unitary structure, it should be understood that the distal end portion **1056** could be formed separately from the remainder of sleeve **1032** and coupled together by any known method such as by fastening, welding or adhesion.

[**0104**] In the illustrated embodiment of the invention, the distal portion **1054** of the outer sleeve **1032** defines a slotted opening **1062** extending transversely through the sidewall of the sleeve **1032** and communicating with the axial cannula passage **1060**. The slotted opening **1062** is sized and shaped to receive the deformable portion **1038** of the inner rod **1030** therethrough when transitioned to the outwardly deformed configuration. Although the outer sleeve **1032** is illustrated as including a single slotted opening **1062**, it should be understood that the outer sleeve **1032** may define any number of slotted openings for receiving a corresponding number of deformable portions associated with the inner rod **1030**.

[**0105**] As discussed above, the handle portion **1024** aids in the manipulation and handling of the instrument **1020** and also includes a mechanism for connecting to a material delivery system. In one embodiment, the handle portion **1024** is generally comprised of a base portion **1070**, a pair of lateral extensions **1072***a*, **1072***b* extending outwardly from the base portion **1070**, and a connector portion **1074** extending proximally from the base portion **1070** in an axial direction. The handle portion **1024** also includes an axial passage **1076** extending through the base portion **1070** and the connector portion **1074**, the purpose of which will be discussed below.

[0106] The outer sleeve **1032** extends distally from the base portion **1070** with the cannula passage **1060** communicating with the axial passage **1076** in the handle portion **1024**. The lateral extensions **1072***a*, **1072***b* extending from the base portion **1070** provide the handle portion **1024** with a T-handle arrangement to aid the surgeon in grasping and manipulating the instrument **1020**. However, it should be understood that other types and configurations of handles are also contemplate for use in association with the instrument **1010**, an example of which will be discussed below in association with another embodiment of a surgical instrument **1120**.

[0107] The connector portion **1074** is configured for attachment to a system **1100** (**FIG. 17**) for delivering material through the instrument **1020** via the axial passage **1076** and the cannula passage **1060** and into a vertebral cavity, the details of which will be discussed below. In the illustrated embodiment, the connector portion **1074** is a lure-type fitting defining external threads **78** adapted for threading engagement with an internally threaded connector element **1102** of the material delivery system **1100** (**FIG. 17**). However, it should be understood that other types and configurations of connector elements suitable for engagement with a material delivery system are also contemplated as falling within the scope of the invention such as, for example, a bayonet-type fitting, a quick-disconnect fitting, or any other suitable connection arrangement.

[0108] As discussed above, the actuator mechanism **1026** serves to selectively transition the deformable strip portion **1038** between the initial and deformed configurations to outwardly expand the deformable strip portion **1038** along the transverse axis T in response to a mechanically induced force provided via selective actuation of the actuator mechanism **1026**. In one embodiment of the invention, the actuator mechanism **1026** is generally comprised of an actuator button **1080**, a biasing member **1082** and a retaining element **1084**. Although a specific embodiment of the actuator mechanism **1026** has been illustrated and described herein, it should be understood that the use of other types and configurations of actuator mechanisms are also contemplated as would occur to one of skill in the art. It should further be understood that in an alternative form of the invention, the inner rod **1030** may be manually engaged by the surgeon, thereby eliminating the need for a separate actuator mechanism **1026**.

[0109] In one embodiment, the actuator button **1080** includes an engaging portion **1080***a*, an intermediate portion **1080***b*, and a spring retaining portion **1080***c*. The intermediate portion **1080***b* has an outer cross section that is somewhat smaller than an outer cross section of the engaging portion **1080***a* so as to define an axially-facing shoulder **1086**. Similarly, the spring retaining portion **1080***c* has an outer cross section that is somewhat smaller than an outer cross section of the intermediate portion **1080***b* so as to define an axially-facing shoulder **1088**. However, it should be understood that other types and configurations of actuator buttons are also contemplated for use in association with the present invention. The actuator rod **1030** extends distally from the actuator button **1080**. In one embodiment, the proximal portion **1034** of the actuator rod **1030** is positioned within an axial passage (not shown) extending at least partially through the actuator button **1080**, with the actuator rod **1030** attached to the actuator button **1080** via a setscrew **1081** or by any other suitable method of attachment.

[0110] In the illustrated embodiment of the invention, the biasing member **1082** is configured as a coil spring. However, it should be understood that other types and configuration of biasing members are also contemplated as would occur to one of ordinary skill in the art. The coil spring **1082** extends about the proximal portion **1034** of the actuator rod **1030**. The distal portion of the spring **1082** is positioned about the connector portion **1074** of the handle **1024** and abuts an axially facing surface **1075** of the handle **1024**. The proximal portion of the spring **1082** is positioned about the spring retaining portion **1080***c* of the actuator button **1080** and abuts the axial shoulder **1088**. As should be appreciated, the connector portion **1074** and the spring retaining portion **1080***c* aid in maintaining the spring **1082** in the appropriate position and orientation relative to the handle portion **1024** and the actuator button **1080**.

[0111] As illustrated in **FIG. 16**, exertion of an axial force F onto the engaging portion **1080***a* of the actuator button **1080** correspondingly exerts an axial force onto the actuator rod **1030**, which in turn axially displaces the actuator rod **1030** in the direction of arrow A. As should be appreciated, the axial force F may be easily and conveniently provided via grasping of the instrument **1020** with fingers wrapped about the lateral extension **1072***a*, **1072***b* of the handle **1024** and with the palm positioned on the engaging portion **1080***a* of the actuator button **1080**. The axial force F is thereby generated by depressing the actuator button **1080** via the surgeon's palm. In this manner, the motion required to generate the axial force F is similar to the motion required to operate a syringe. As should also be appreciated, axial displacement of the actuator button **1080** in the direction of arrow A correspondingly compresses the coil spring **1082** between the handle **1024** and the actuator button **1080**, the purpose of which will be discussed below.

[0112] Displacement of the actuator rod **1030** in the direction of arrow A results in axial compression of the deformable strip portion **1038** via opposing forces exerted onto the strip portion **1038** by the movable main body portion **1036** and the stationary distal end portion **1040** of the actuator rod **1030**. The axial compression force exerted onto the strip portion **1038** in turn causes the strip portion **1038** to outwardly expand or buckle/bow along the transverse axis T. Outward expansion of the strip portion **1038** causes the strip portion **1038** to project through the transverse opening **1062** in the outer sleeve **1032**. As should be appreciated, the degree of outward expansion of the strip portion **1038** and the magnitude of the expansion force generated along the transverse axis T can be selectively and accurately controlled by varying the amount of axial force F exerted onto the actuator button **1080**. In other words, the amount of axial force F exerted onto the actuator button **1080** by the surgeon is proportional to the degree of outward expansion and the magnitude of the expansion force associated with the strip portion **1038**.

[0113] Upon removal of the axial force F from the actuator button **1080** via loosening of the surgeon's grip on the engaging portion **1080***a* and the lateral extensions **1072***a*, **1072***b*, the biasing force exerted by the compressed coil spring **1082** onto the actuator button **1080** will correspondingly displace the actuator button **1080** and the actuator rod

1030 in the direction of arrow B. Displacement of the actuator rod **1030** in the direction of arrow B results in removal of the axial compression force on the strip portion **1038**, which in turn results in reformation of the strip portion **1038** from the outwardly deformed configuration illustrated in **FIG. 16** back toward the initial configuration illustrated in **FIG. 13**.

[**0114**] Referring once again to **FIG. 14**, in one embodiment of the invention, the retaining element **1084** is configured to selectively retain the actuator button **1080** and the actuator rod **1030** in a non-actuated position to avoid unintentional deployment or transitioning of the deformable strip portion **1038** toward the outwardly expanded configuration. In the illustrated embodiment, the retaining element **1084** has a clip-like configuration defining a horseshoe shape. However, other shapes and configurations of the retaining elements suitable for selectively maintaining the actuator button **1080** and the actuator rod **1030** in a non-actuated position are also contemplated as falling within the scope of the present invention.

[**0115**] In the illustrated embodiment, the retaining element **1084** has a generally cylindrical sidewall **1090** defining an axial passage **1092** therethrough, and an axial slot **1094** extending the length of the sidewall **1090** so as to define a crosswise opening **1096** communicating with the axial passage **1092**. A pair of extension portions or flanges **1098***a*, **1098***b* extend from the cylindrical sidewall **1090** in an outwardly tapering manner adjacent the crosswise opening **1096**. The crosswise opening **1096** has a minimum opening width that is slightly less than the outer diameter of the intermediate portion **1080***b* of the actuator button **1080**. Additionally, the retaining element **1084** has a length that is substantially equal to the distance between the axially-facing surface **1075** of the handle **1024** and the axially-facing shoulder **1086** of the actuator button **1080**.

[**0116**] As should be appreciated, the retaining element **1084** is engagable with the remainder of the instrument **1020** by aligning the crosswise opening **1096** with the proximal portion **1034** of the actuator rod **1030** and transversely displacing the retaining element **1084** to a position between the handle **1024** and the actuator button **1080**. The outwardly tapered extension portions **1098***a*, **1098***b* of the retaining element **1084** serve to guide the proximal portion **1034** of the actuator rod and the intermediate potion **1080***b* of the actuator button into the axial passage **1092**. As should also be appreciated, since the width of the crosswise opening **1096** is sized slightly less than the outer diameter of the intermediate portion **1080***b*, the sidewall **1090** of the retaining element **1084** is slightly outwardly deformed to receive the intermediate portion **1080***b* through the crosswise opening **1096**. Once the intermediate portion **1080***b* is positioned within the axial passage **1092**, the sidewall **1090** snaps back into its undeformed condition, thereby selectively engaging the retaining element **1084** to the actuator button **1080**. As should further be appreciated, positioning of the retaining element **1084** between the axially-facing surface **1075** of the handle **1024** and the axially-facing shoulder **1086** of the actuator button **1080** selectively retains the actuator button **1080** and the actuator rod **1030** in a non-actuated or non-deployed position.

[**0117**] Having described the components and features associated with the instrument **1020**, reference will now be made to a method for using the instrument **1020** in the treatment of a portion of the spine according to one form of the present invention. However, it should be understood that other uses of the instrument **1020** are also contemplated as falling within the scope of the present invention.

[**0118**] Referring to **FIG. 15**, shown therein is a posterior view of a portion of a spinal column with the distal portion **1022***a* of the instrument **1020** being inserted through an access portal P formed through an outer wall of the vertebral body V_1. As discussed above, the retaining element **1084** prevents unintentional deployment or transitioning of the distal portion **1022***a* of the instrument **1020** toward the outwardly expanded configuration during the initial introduction into the vertebral body V_1. As should also be appreciated, the distal portion **1022***a* is inserted into the vertebral body V_1 while in the non-expanded initial configuration so as to define a minimal cross-sectional area to minimize the size of the access portal P. When in the non-expanded initial configuration, the distal end portion **1022***a* has a relatively low profile to facilitate positioning adjacent a vertebral body. As used herein, positioning of the distal end portion **1022***a* adjacent a vertebral body is meant to include positioning of the distal end portion **1022***a* in proximity to a vertebral body, within a vertebral body or within a space between adjacent vertebral bodies. In one embodiment of the invention, the initial configuration of the distal end portion **1022***a* is sized to pass through an access portal having a diameter between about 1 millimeter and about 10 millimeters. In a specific embodiment, the initial configuration of the distal end portion **1022***a* is sized to pass through an access portal having a diameter of about 5 millimeters. However, other sizes are also contemplated as falling within the scope of the present invention.

[**0119**] In the illustrated embodiment, entry into the vertebral body V_1 is accomplished via a posterior approach and occurs through the pedicle region of the vertebral body V_1. Additionally, entry into the vertebral body V_1 could be either extra-pedicular or trans-pedicular. However, it should be understood that in other embodiments of the invention, entry into the vertebral body V_1 may be accomplished via other surgical approaches such as, for example, an anterior or lateral approach, and could occur through other portions of the vertebral body. Additionally, as indicated above, the instrument **1020** may also be used in interbody applications such as, for example, to distract a portion of the intervertbral space between the adjacent vertebral bodies V_1, V_2.

[**0120**] In one embodiment of the invention, access into the inner region of the vertebral body V_1 is accomplished by drilling a relatively small access portal P through an outer wall of the vertebral body V_1. The undeformed initial configuration of the distal end portion **1022***a* of the instrument **1020** is sized to pass through the small access portal P to gain access to the inner cancellous region of the vertebral body V_1. In this manner, insertion of the distal end portion **1022***a* into the vertebral body V_1 is accomplished in a minimally invasive manner. In another embodiment of the invention, access into the inner region of the vertebral body V_1 may be accomplished by driving the pointed tip or trocar portion **1058** of the instrument **1020** into the vertebral body V_1 to form the access portal P via an impaction technique. As should be appreciated, with the retaining element **1084** engaged between the handle **1024** and the actuator button **1080**, an impaction force can be exerted onto the engaging

portion **1080***a* of the actuator button **1080** to drive the distal portion **1022***a* into the vertebral body V_1 while avoiding transitioning of the deformable strip portion **1038** toward the outwardly expanded configuration.

[**0121**] Referring to **FIG. 16**, once the distal portion **1022***a* is properly positioned adjacent or within the vertebral body V_1, the retaining element **1084** is removed from the instrument **1020** to allow for selective actuation or deployment of the instrument **1020**. Specifically, the distal portion **1022***a* is transitioned from the initial insertion configuration illustrated in **FIG. 15** to the outwardly deformed configuration illustrated in **FIG. 16** via exertion of an axial force F onto the engaging portion **1080***a* of the actuator button **1080** to correspondingly displace the actuator rod **1030** in the direction of arrow A. Axial displacement of the actuator rod **1030** in the direction of arrow A in turn outwardly deforms the distal portion **1022***a* along the transverse axis T. More specifically, axial compression of the deformable strip portion **1038** causes the strip portion **1038** to outwardly buckle or bow and project through the transverse opening **1062** in the sleeve **1032** so as to define a transverse projection or deformation along the transverse axis T. Since the illustrated embodiment of the instrument **1020** defines a single transverse projection that extends in a single direction, formation of the transverse projection and the resulting preparation of the vertebral body is said to be unidirectional or directionally controlled.

[**0122**] It should be understood, however, that the instrument **1020** may be configured to include multiple transverse projections. In another embodiment, the instrument **1020** may be configured to include a pair of transverse projections extending in generally opposite directions and aligned along a common transverse axis T. In this alternative embodiment, formation of the transverse projections and the resulting preparation of the vertebral body would be described as uniaxial or axially controlled. Although not specifically illustrated herein, it should also be understood that the instrument **1020** may also be configured to include multiple transverse projections positioned at various axial locations along the longitudinal axis L.

[**0123**] As discussed above, outward deformation of the distal portion **1022***a* along the transverse axis T may be used to compact or compress cancellous bone against the inner cortical wall of the vertebral body to form an intervertebral cavity C therein. Compaction of the cancellous bone also exerts an outward force on the inner surface of the cortical wall adjacent the endplates and/or lateral walls of the vertebral body V_1, thereby making it possible to elevate or push broken and/or compressed bone back to or near its original pre-fracture condition or another desired condition. The deformed distal portion **1022***a* may also bear directly against the inner surface of the cortical bone to reduce a compression fracture in the vertebral body V_1.

[**0124**] As discussed above, other uses of the instrument **1020** include, for example, distraction of the adjacent vertebral bodies to increase the height of the intervertebral disc space D and/or displacement a spinal implant or other structures used in association with treatment of the spine.

[**0125**] In one embodiment of the invention, the outwardly deformed configuration of the distal portion **1022***a* has an overall height h along the transverse axis T (as measured from the longitudinal axis L) that falls within a range of about 3 millimeters to about 15 millimeters. In a specific embodiment, the outwardly deformed configuration of the distal portion **1022***a* has an overall height h of about 7 millimeters. In another specific embodiment of the invention, the instrument **1020** is capable of assuming a deformed configuration having an overall height h that is at least two to three times that of the height of the initial configuration. In another embodiment of the invention, the outwardly deformed configuration of the distal portion **1022***a* has a length l (as measured along the longitudinal axis L) falling within a range of about 10 millimeters to about 40 millimeters. In a specific embodiment, the outwardly deformed configuration of the distal portion **1022***a* has an overall length l of about 25 millimeters. Although ranges and specific sizes of the initial and deformed configurations of distal end potion **1022***a* of the instrument **1020** have been set forth above, it should be understood that such ranges and sizes are exemplary and do not limit the scope of the present invention in any manner whatsoever.

[**0126**] Following formation of the intervertebral cavity C in the vertebral body V_1, the distal end portion **1022***a* of the instrument **1020** is reformed back toward the initial configuration by displacing the actuator rod **1030** in the direction of arrow B. As discussed above, upon the removal of the axial force F from the actuator button **1080**, the biasing force exerted by the compressed coil spring **1082** onto the actuator button **1080** will correspondingly displace the actuator button **1080** and the actuator rod **1030** in the direction of arrow B. Displacement of the actuator rod **1030** in the direction of arrow B results in removal of the axial compression force on the strip portion **1038**, which in turn results in reformation of the distal portion **1022***a* from the outwardly deformed configuration illustrated in **FIG. 16** back toward the initial configuration illustrated in **FIG. 13**. As also discussed above, reformation of the distal portion **1022***a* back toward the initial configuration may be facilitated by forming at least the strip portion **1038** of a shape-memory material. Once transitioned back to the initial configuration, the distal portion **1022***a* of the instrument **1020** can be relocated to a different position and/or rotated to a different angular orientation. The instrument **1020** can then be reactivated or redeployed by once again exerting an axial force F onto the actuator button **1080** to outwardly deform the distal portion **1022***a* along the transverse axis T to enlarge the intervertebral cavity C and/or to form another intervertebral cavity C within the vertebral body V_1.

[**0127**] Following formation of the intervertebral cavity or cavities C, the distal portion **1022***a* of the instrument **1020** is transitioned back toward the initial configuration illustrated in **FIG. 13**. In one embodiment of the invention, the instrument **1020** is then removed from the vertebral body V_1. However, as illustrated in **FIG. 17**, in another embodiment of the invention the inner actuator rod **1030** is removed from the outer sleeve **1032** to define a hollow cannula passage **1060** communicating between the transverse opening **1062** and the axial passages **1076** in the connector portion **1074** of the handle **1024**. A material delivery system **1100** may then be attached to the connector portion **1074** to deliver a material M into the axial passage **1076**, through the hollow cannula **1060**, out the transverse opening **1062** and into the vertebral cavity or cavities C.

[**0128**] Although the illustrated embodiment of the invention depicts the outer sleeve **1032** as defining a single

transverse opening **1062** for delivery of the material M into the vertebral cavity C, it should be understood that the sleeve **1032** may define any number of transverse or axial openings for delivery of material M therethrough. It should also be understood that the outer sleeve **1032** may define other types and configurations of delivery openings such as, for example, a plurality of substantially circular opening having a relatively smaller cross section than that of the transverse opening **1062**.

[**0129**] As shown in **FIG. 17**, the material M is delivered into the intervertebral cavity or cavities C to aid in the fixation and structural support of the vertebral body V_1. In one embodiment of the invention, the material M comprises a flowable material that is settable or curable following introduction into the cavity C. Once set to a hardened condition, the material M provides internal structural support to the vertebral body V_1, and more particularly provides structural support to the cortical bone of the vertebral body V_1. In a specific embodiment, the material M comprises a biocompatible filling material such as, for example, a bone cement or various types of synthetic bone material. In another specific embodiment, the material comprises methylmethacrylate cement. However, it should be understood that the material M may comprise other types of materials including, for example, a therapeutic substance to promote healing, a bone growth promoting substance, and/or one or more bone implant support structures.

[**0130**] Although not specifically illustrated in **FIGS. 16 and 17**, it should be understood that in a further embodiment of the invention, a cannula assembly may be used to provide minimally invasive access to the vertebral bodies V_1, V_2 and/or to the intervertebral disc space D. As should be appreciated, use of a cannula assembly would permit preparation of vertebral tissue via insertion and manipulation of the instrument **1020** and other instrumentation or device through a single working channel.

[**0131**] Referring to **FIG. 18**, shown therein is an instrument **1120** for treatment of the spine according to another form of the present invention. The instrument **1120** is used in association with applications such as those discussed above with regard to the instrument **1020**, and is particularly useful for placement adjacent a spinal structure to selectively displace at least a portion of the spinal structure. In many respects, the illustrated embodiment of the instrument **1120** is structurally and functionally similar to the instrument **1020** illustrated and described above. Accordingly, like elements and features are indicated and referred to using the same reference numerals.

[**0132**] Similar to the instrument **1020**, the instrument **1120** is generally comprised of an elongate member **1022**, a handle portion **1124**, an actuator mechanism **1126**, and a deformable portion **1028** that is selectively transitionable between an initial configuration (shown in solid lines) and a deformed configuration (shown in phantom lines). The elongate member **1022** extends generally along a longitudinal axis L and has a distal portion **1022***a* and a proximal portion **1022***b*. The handle portion **1124** aids in the manipulation and handling of the instrument **1120** and also includes a mechanism for connecting to a material delivery system, the detail of which will be discussed below. The actuator mechanism **1126** serves to transition the deformable portion **1028** between the initial and deformed configurations. The deformable portion **1028** is positioned adjacent the distal portion **1022***a* of the elongate member **1022** and outwardly expands along the transverse axis T in response to a mechanically induced force that is provided via selective actuation of the actuator mechanism **1126**.

[**0133**] In the illustrated embodiment, the handle portion **1124** and the actuator mechanism **1126** have a kerrison-type configuration. Specifically, the handle portion **1124** is generally comprised of a base portion **1170**, a grip portion **1172**, and a connector portion **1174**. The handle portion **1124** includes an axial passage (not shown) extending through the base portion **1170** and the connector portion **1174**, with the outer sleeve **1032** extending distally from the base portion **1170**. The cannula passage of the outer sleeve **1032** communicates with the axial passage extending through the base portion **1170** and the connector portion **1174**. The grip portion **1172** aids the surgeon in grasping and manipulating the instrument **1120**. The connector portion **1174** is configured for attachment to a system **1100** (**FIG. 17**) for delivering a material M through the instrument **1120** and into one or more vertebral cavities C. In the illustrated embodiment, the connector portion **1174** comprises a lure-type fitting defining external threads **1178** adapted for threading engagement with an internally threaded connector element **1102** of the material delivery system **1100** (**FIG. 17**). However, it should be understood that other types and configurations of connector elements suitable for engagement with a material delivery system are also contemplated as falling within the scope of the invention such as, for example, a bayonet-type fitting, a quick-disconnect fitting, or any other suitable connection arrangement.

[**0134**] As discussed above, the actuator mechanism **1126** serves to selectively transition the deformable strip portion **1038** between the initial and deformed configurations to outwardly expand the deformable strip portion **1038** along the transverse axis T in response to a mechanically induced force provided via selective actuation of the actuator mechanism **1126**. In one embodiment of the invention, the actuator mechanism **1126** is generally comprised of an actuator or trigger portion **1180** and a biasing member **1190**. Although not specifically illustrated in **FIG. 18**, the actuator mechanism **1126** may also include a retaining element configured to selectively retain the trigger portion **1180** and the actuator rod **1030** in a non-actuated position to avoid unintentional deployment or transitioning of the deformable strip portion **1038** toward the outwardly expanded configuration. The trigger portion **1180** generally includes a grip portion **1182** and a coupler portion **1184**. The grip portion **1182** is pivotally attached to the grip portion **1172** of the handle **1124** via a pivot pin **1186** to allow for relative pivotal movement therebetween in the direction of arrows A and B. The grip portion **1182** is pivotally attached to the coupler portion **1184** via a pivot pin **1188** to provide pivotal engagement between the proximal end **1034** of the actuator rod **1030** and the grip portion **1182**.

[**0135**] In the illustrated embodiment, the biasing member **1190** is configured as a U-shaped strip-like spring element. However, it should be understood that other types and configuration of biasing members are also contemplated as would occur to one of ordinary skill in the art including, for example, a coil spring. The spring **1190** is engaged between the grip portions **1172**, **1182** and serves to bias the grip portions **1172**, **1182** apart to maintain the instrument **1120** in

a non-actuated or non-deployed configuration. However, exertion of a force F onto the grip portion **1182** causes the grip portion **1182** to pivot in the direction of arrow A, which in turn exerts an axial force onto the proximal portion **1034** of the actuator rod **1030** to displace the actuator rod **1030** in the direction of arrow C. Displacement of the actuator rod **1030** in the direction of arrow C results in axial compression of the deformable strip portion **1038**, which in turn causes the strip portion **1038** to outwardly expand or buckle/bow along the transverse axis T. As should be appreciated, the degree of outward expansion of the strip portion **1038** and the magnitude of the expansion force generated along the transverse axis T can be selectively and accurately controlled by varying the amount of force F exerted onto the grip portion **1182**. In other words, the amount of force F exerted onto the grip portion **1182** by the surgeon is proportional to the degree of outward expansion and the magnitude of the expansion force associated with the deformed strip portion **1038**.

[**0136**] In the illustrated embodiment, the force F exerted onto the grip portion **1182** is provided via grasping of the instrument **1120** with fingers wrapped about the grip portion **1182** and with the palm and/or thumb positioned on the grip portion **1172**. The axial force F is thereby generated by squeezing the grip portion **1182** toward the grip portion **1172**. As should be appreciated, pivotal movement of the grip portion **1182** in the direction of arrow A correspondingly compresses the spring element **1190** between the grip portions **1172**, **1182**. As should also be appreciated, upon removal of the force F via loosening of the surgeon's grip on the grip portion **1182**, the biasing force exerted by the compressed spring **1190** will correspondingly displace the grip portion **1182** in the direction of arrow B, which in turn displaces the actuator rod **1030** in the direction of arrow D. Displacement of the actuator rod **1030** in the direction of arrow D results in removal of the axial compression force on the strip portion **1038**, which in turn results in reformation of the strip portion **1038** from the outwardly deformed configuration (as shown in phantom lines) back toward the initial configuration (as shown in sold lines).

[**0137**] In some embodiments of the invention, the deformable strip **1038** may be designed to provide a cutting edge **1055** that is exposed to cut tissue when the deformable strip **1038** is extended. The cutting edge **1055** may be a thin portion of the deformable strip **1038**, or in some embodiments may be sharpened to an edge that is significantly thinner than the thickness of the deformable strip **1038** to provide a sharper cutting edge. The cutting edge may be tempered, serrated, or otherwise treated or configured to enhance the ability of the projections to cut through tissue, as is known in the art of tissue cutting devices.

[**0138**] Similar to the instrument **1020** illustrated and described above, the instrument **1120** is configured to allow for removal of the inner actuator rod **1030** from the outer sleeve **1032** to provide an axial passageway **1060** for the delivery of a material M into the intervertebral cavity C formed within the vertebral body V_1. Specifically, following transitioning of the distal portion **1022***a* of the instrument **1120** back to the initial configuration, the actuator rod **1030** is removed from the outer sleeve **1032** to define a hollow cannula **1060** communicating between the transverse slotted opening **1062** and the connector portion **1074**. A material delivery system **1100** (**FIG. 17**) may then be attached to the connector portion **1074** to deliver a material M through the hollow cannula **1060**, out the transverse opening **1062** and into the vertebral cavity C.

[**0139**] As should now be appreciated, in the illustrated embodiments of the invention, the instruments **1020**, **1120** are capable of performing multiple functions associated with treatment of the spine. For example, the trocar **1058** facilitates entry into and through vertebral tissue. Additionally, the deformable distal portion **1022***a*, and more specifically the deformable strip portion **1038**, serves to reduce a vertebral fracture and/or to form one or more intervertebral cavities C with the vertebral body V_1. Further, upon the selective removal of the inner actuator rod **1030**, the outer sleeve **1032** provides a hollow cannula **1060** for delivering a material M into the intervertebral cavity C. As should be appreciated, the use of a single instrument to perform multiple functions associated with a spinal treatment procedure tends to simplify the surgical procedure, lessen the time required to perform the procedure, and/or reduce the costs and expenses compared to providing multiple surgical instruments to perform similar functions. Additionally, if the instrument **1020**, **1120** is designed as a single use instrument, the cost associated with sterilizing the instrument **1020**, **1120** for reuse are eliminated.

[**0140**] Another embodiment of the invention is illustrated in **FIGS. 19-27**. Instrument **1220** is configured for treatment of the spine according to another form of the present invention. The instrument **1220** is used in association with applications such as those discussed above with regard to the instrument **1020**, and is particularly useful for placement adjacent a spinal structure to selectively prepare or displace at least a portion of the spinal structure.

[**0141**] Similar to the instrument **1020**, the instrument **1220** (**FIG. 25**) is generally comprised of an elongate member **1222**, a handle portion **1224**, an actuator mechanism **1226**, and a deformable portion **1228** that is selectively transitionable between an initial configuration and a deformed configuration. The elongate member **1222** extends generally along a longitudinal axis L and has a distal portion **1222***a* and a proximal portion **1222***b*. The handle portion **1224** aids in the manipulation and handling of the instrument **1220**. The actuator mechanism **1226** serves to transition the deformable portion **1228** between the initial and deformed configurations. The deformable portion **1228** is positioned adjacent the distal portion **1222***a* of the elongate member **1222** and outwardly expands along the transverse axis T in response to a mechanically induced force that is provided via selective actuation of the actuator mechanism **1226**.

[**0142**] Referring now to **FIGS. 19-21**, the handle portion **1224** includes an axial passage **1225** extending through the base portion **1270**, with the outer sleeve **1232** extending distally from the base portion **1270**. The cannula passage of the outer sleeve **1232** communicates with the axial passage extending through the base portion **1270**. The grip portion **1272** aids the surgeon in grasping and manipulating the instrument **1220**.

[**0143**] As discussed above, the actuator mechanism **1226** serves to selectively transition a deformable strip portion **1238** of the deformable portion **1228** between the initial and deformed configurations to outwardly expand the strip **1238** along the transverse axis T in response to a mechanically induced force provided via selective actuation of the actuator mechanism **1226**.

[0144] In the embodiment illustrated in **FIG. 25**, a force F exerted onto the grip portion **1282** is provided via grasping of the instrument **1220** with fingers wrapped about the grip extensions **1272***a*, **1272***b* and with the palm positioned on the grip portion **1282**. The axial force F is generated by squeezing the grip portion **1282** toward the grip extensions **1272***a*, **1272***b*. The axial force F thereby transfers force through the inner actuator rod **1230** and transitions the strip portion **1238** to a deformed configuration. As should also be appreciated, upon removal of the force F via loosening of the surgeon's grip on the grip portion **1282**, the biasing force exerted by the strip portion **1238** will correspondingly displace the grip portion **1282** proximally. In this manner, the strip portion **1238** also acts as a spring.

[0145] In some embodiments of the invention, the deformable strip **1238** may be designed to provide a cutting edge **1255** that is exposed to cut tissue when the deformable strip **1238** is extended. The cutting edge **1255** may be a thin portion of the deformable strip **1238**, or in some embodiments may be sharpened to an edge that is significantly thinner than the thickness of the deformable strip **1238** to provide a sharper cutting edge. The cutting edge may be tempered, serrated, or otherwise treated or configured to enhance the ability of the projections to cut through tissue, as is known in the art of tissue cutting devices.

[0146] Similar to the instrument **1020** illustrated and described above, the instrument **1220** is configured to allow for removal of the inner actuator rod **1030** from the outer sleeve **1232** to provide an axial passage **1225** (**FIGS. 20-21**) for the delivery of a material M into the spinal structure. Specifically, following transitioning of the distal portion **1222***a* (including strip portion **1238**) of the instrument **1220** back to the initial configuration, the actuator rod **1230** is removed from the outer sleeve **1232** to define an axial passage **1225** communicating between a transverse slotted opening **1262** and the proximal end of elongated member **1222** (**FIGS. 26 and 27**). A material delivery system **1200**, such as an injector, may then be used to deliver a material M through the axial passage **1225** and out of the transverse slotted opening **1262** and/or the distal opening **1263**. In the illustrated embodiment, the material M is being delivered through a delivery tube **1201** that is connected to the material delivery system **1200**.

[0147] As should now be appreciated, in the illustrated embodiments of the invention, the instrument **1220** is capable of performing multiple functions associated with treatment of the spine. For example, **FIG. 24** shows a stylet **1258** for facilitating entry into and through vertebral tissue. The stylet **1258** is insertable in the elongated member **1222** and the combined devices are used to locate an access point and to enter vertebral tissue. The stylet **1258** and the elongated member **1222** connect together via the locking mechanism **1204**. Locking mechanism **1204** includes a catch **1205** that locks into hole **1206** (**FIG. 20**) when stylet **1258** is inserted into elongated member **1222**. When proper positioning is achieved, the stylet **1258** can be removed from the elongated member **1222** and the elongated member **1222** can remain in place to provide a cannula into the vertebral tissue.

[0148] Each of the handle **1259** of the stylet **1258** and the grip portion **1282** include alignment markings **1207** that indicate to a user the proper alignment of the devices in the elongated member **1222**. The elongated member includes a corresponding alignment base **1208** which, when aligned with the alignment markings **1207** of the appropriate device, ensures correct assembly of the instrument.

[0149] Additionally, the deformable distal portion **1222***a*, and more specifically the deformable strip portion **1238**, may be used to loosen or cut vertebral tissue to reduce a vertebral fracture and/or to form one or more intervertebral cavities in a vertebral body. As should be appreciated, the use of a single instrument to perform multiple functions associated with a spinal treatment procedure tends to simplify the surgical procedure, lessen the time required to perform the procedure, and/or reduce the costs and expenses compared to providing multiple surgical instruments to perform similar functions. Additionally, if the instrument **1220** is designed as a single use instrument, the costs associated with sterilizing the instrument **1220** for reuse are eliminated.

[0150] Embodiments of the invention include various methods of use of the disclosed devices. The various methods may be operable with one or more of the instruments of the disclosed embodiments of the invention.

[0151] In one method embodiment, treatment of the spine is accomplished by use of an instrument defining a cannula passage extending along a longitudinal axis and including a deformable distal portion having an insertion configuration and a deformed configuration. For example, the instruments of at least **FIGS. 13, 18**, and **25** would provide such features.

[0152] In some embodiments, the spine is treated by at least the acts of providing an instrument defining a cannula passage extending along a longitudinal axis and including a deformable distal portion having an insertion configuration and a deformed configuration. Further, the distal portion of the instrument is positioned within a spinal structure while in the insertion configuration, and the instrument is activated to loosen tissue within the spinal structure. A material may then be delivered through the cannula passage and into the spinal structure.

[0153] In accomplishing certain method embodiments, the distal portion of an instrument is positioned within a spinal structure while in an unexpanded or "insertion configuration." Actuation of an instrument then transitions the distal portion of the instrument toward an expanded or deformed configuration. Simultaneously with the expansion of the instrument, the instrument is rotated about the longitudinal axis. Rotation of the expanding instrument contacts tissue in the path of the expanded components and loosens tissue within the spinal structure. In some embodiments, loosened material is removed by either suction or mechanical engagement with the loosened material. Equipment to generate a suction force is available in many operating rooms through a tubing suction system. Alternatively, suction may be generated with a syringe or by any other effective means.

[0154] In some method embodiments, the interior of a vertebral body or other structure is irrigated with a fluid to manipulate the contents of the structure. For example, a solution may be used to clean the inside of a vertebral body. The solution may be injected through the cannula to suspend loosened material within the vertebral body, and then suctioned back through the cannula. Alternatively, the suctioning may be provided simultaneously with the injection of the fluid. By way of example, the fluid may be provided through

a cannula inserted through one pedicle while a suction tube inserted through the contralateral pedicle removes fluid.

[0155] One or more fluids may be injected to created desirable therapeutic results. A saline solution could be used to clean the inside of a vertebral body by circulation though the vertebral body. Subsequently, another fluid such as, for example, air or inert gas may be injected into or circulated through the vertebral body. The additional fluid may be, without limitation, effective to facilitate hemostasis, to better prepare the vertebral body to accept a therapeutic agent, or to dry the tissue within the vertebral body. One or more of the fluids used may contain biologically and/or chemically active substances useful to create a desired clinical result.

[0156] With a loosened or evacuated volume within the spinal structure created, material may be delivered through the cannula passage and into the spinal structure. Several specific and adequate bone fillers are detailed in the disclosure, and additionally, the delivered material may be any material that creates a positive therapeutic result for a patient.

[0157] For the purposes of the following description, transitioning the deformable distal portion to a deformed configuration will be referred to as expanding the instrument, and transitioning the distal portion substantially to the insertion configuration will be referred to as returning to the insertion configuration. Note that the instrument need not be returned to precisely the same degree of expansion as when inserted to be returned to the insertion configuration as used herein. Loosening of the tissue within the spinal structure may be accomplished by expanding the instrument in a first location, returning the instrument to the insertion configuration, and rotating the instrument about the longitudinal axis to a second location. In the second location, the instrument is again expanded. While expanded, the instrument is rotated about the longitudinal axis at least to the first location. This procedure may be repeated one or more times to create a volume of loosened tissue.

[0158] Loosening of the tissue within the spinal structure may also be accomplished by expanding the instrument and rotating the instrument one or more revolutions as needed to loosen the tissue.

[0159] Loosening of the tissue within the spinal structure may additionally be accomplished by expanding the instrument and rotating the instrument any degree of rotation about the longitudinal axis. The instrument may then be expanded to a second deformed configuration that has a greater transverse deformation or is larger. In the position of larger expansion, the instrument is again rotated to some degree about the longitudinal axis. Such a technique may be beneficial where the method is accomplished in a patient with relatively strong bony structure that produces greater resistance to rotation.

[0160] Loosening of the tissue within the spinal structure may additionally be accomplished by expanding and rotating the instrument about the longitudinal axis, and then changing the degree of the expansion to a second deformed configuration. The second deformed configuration may be greater or lesser than the first expansion. In the second configuration, the instrument is rotated about the longitudinal axis. This procedure may be useful to avoid certain portions with a body being loosened, when the instrument is not symmetrically placed in the bony structure, and at other times.

[0161] In another embodiment, treatment of the spine is accomplished by use of an instrument defining a cannula passage extending along a longitudinal axis and including a deformable distal portion having an insertion configuration and a deformed configuration. The distal portion of the instrument is positioned within a spinal structure while in the insertion configuration. The instrument is expanded, returned to its insertion configuration, and then rotated about the longitudinal axis. In the new position, the instrument is expanded and released again. This expansion, release, and rotation is repeated until the deformable distal portion has been deployed to contact more than half of the radial surface of the interior of the spinal structure. When the material inside the spinal structure has been manipulated as desired, material is delivered through the cannula passage and into the spinal structure. This embodiment is useful, among other functions, to move tissue away from the center of the spinal structure.

[0162] Another method of the invention is designed to enhance the placement of filler material within a spinal structure in an effective manner. The method includes providing an instrument with a cannula passage extending along a longitudinal axis. The distal portion of the instrument is positioned within a spinal structure. A first portion of filler material is delivered through a tube extended through the cannula to a distal end of the accessible portion of the spinal structure. In some embodiments, this delivery may be monitored with fluoroscopy, endoscopy, or by any effective means. The tube is withdrawn proximally relative to the cannula when deemed appropriate by the surgeon. In some cases, the withdrawal of the tube will allow the filler material to be more directly placed near its final position and therefore prevent the building of pressure in the spinal structure during a procedure. In a withdrawn position, a second portion of filler material is delivered through the tube and into the spinal structure.

[0163] Another embodiment of the invention is an actuator for manipulating tissue. The actuator includes at least a first member extending in the direction of a longitudinal axis and a second member extending in the direction of the longitudinal axis. The first member and the second member are movable relative to one another along some portion in the direction of the longitudinal axis. Embodiments of the actuator have a deformable distal portion of the actuator with a strip with a greatest dimension substantially in the direction of the longitudinal axis. The strip buckles to create a transverse projection when the first member and the second member are moved relative to one another in the direction of some portion of the longitudinal axis. The strip also has a cutting edge that is exposed to the tissue when the first member and the second member are moved relative to one another along some portion in the direction of the longitudinal axis.

[0164] While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character.

What is claimed is:

1. A kit for treatment of the spine, comprising:

a cannula for maintaining a passageway to a portion of the spine to be treated;

a surgical instrument for providing surgical access to the spine, the instrument being operable through the cannula;

a bone filler injector; and

a tube that provides a conduit between the bone filler injector and the cannula;

wherein the tube is extendable through the cannula to a position adjacent to the portion of the spine to be treated.

2. The kit of claim 1 wherein at least a portion of a distal end of the cannula has an opening through which the instrument operates.

3. The kit of claim 2 wherein the opening is in a distal most portion of the distal end of the cannula.

4. The kit of claim 1 wherein the surgical instrument is a stylet.

5. The kit of claim 1 wherein the surgical instrument is a spring.

6. The kit of claim 1 wherein the bone filler injector provides bone filler at a controlled pressure and volume.

7. The kit of claim 1 wherein the tube has an outside diameter of greater than 0.5 mm less than the inside diameter of the cannula.

8. The kit of claim 1 wherein the cannula has an opening through which a bone filler material is injectable into the spine.

9. The kit of claim 8 wherein the opening is in a distal most portion of the distal end of the cannula.

10. The kit of claim 1 wherein the cannula has an opening through which the tube may be extended.

11. The kit of claim 10 wherein the opening is in a distal most portion of the distal end of the cannula.

12. The kit of claim 1 wherein the tube is a flexible tube.

13. A method of performing a biopsy, comprising:

providing a medical instrument comprising:

a cannula member extending along a longitudinal axis and including a distal portion, said cannula member defining an axial passage and a transverse opening positioned adjacent said distal portion and communicating with said axial passage; and

an actuator member removably positioned within said axial passage of said cannula member and including a deformable portion positioned adjacent said transverse opening, said deformable portion being transitionable between an initial configuration for placement within a spinal structure and a deformed configuration defining a transverse projection extending through said transverse opening in said cannula member; and

selectively removing tissue on which a biopsy is to be accomplished from said cannula member.

14. A method for treatment of the spinet comprising:

providing an instrument defining a cannula passage extending along a longitudinal axis and including a deformable distal portion having an insertion configuration and a deformed configuration;

positioning the distal portion of the instrument within a spinal structure while in the insertion configuration;

transitioning the distal portion of the instrument toward the deformed configuration while simultaneously rotating the instrument about the longitudinal axis to form a volume of loosened tissue within the spinal structure; and

delivering a material through the cannula passage and into the spinal structure.

15. The method of claim 14 further comprising removing a portion of the loosened tissue from the spinal structure prior to delivering a material into the spinal structure.

16. The method of claim 15 wherein removing a portion of the loosened tissue includes suctioning loosened tissue.

17. The method of claim 15 wherein removing a portion of the loosened tissue includes mechanically removing loosened tissue.

18. A method for treatment of the spine, comprising:

providing an instrument defining a cannula passage extending along a longitudinal axis and including a deformable distal portion having an insertion configuration and a deformed configuration;

positioning the distal portion of the instrument within a spinal structure while in the insertion configuration;

activating the instrument to loosen tissue within the spinal structure;

removing a portion of the loosened tissue from the spinal structure; and

delivering a material through the cannula passage and into the spinal structure.

19. The method of claim 18 further comprising injecting a fluid into the spinal structure to prepare the structure to receive a delivered material.

20. The method of claim 19 wherein injecting a fluid includes injecting a liquid.

21. The method of claim 19 wherein injecting a fluid includes injecting a gas.

22. A method for treatment of the spine, comprising:

providing an instrument defining a cannula passage extending along a longitudinal axis;

positioning the distal portion of the instrument within a spinal structure while in the insertion configuration;

delivering a first portion of filler material through a tube extended through the cannula to a distal end of an accessible portion of the spinal structure;

withdrawing the tube proximally relative to the cannula; and

delivering a second portion of filler material through the tube and into the spinal structure.

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